

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 862, 864, 866, 868, 870, 872, 874, 876, 878, 880, 882, 884, 886, 888, 890, and 892

[Docket No. 01N-0073]

Medical Devices; Exemption From Premarket Notification Requirements; Class I Devices; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the language in its medical device classification regulations for class I devices for consistency, to include in sections where it was not present, a specific reference to the limitations on exemptions from premarket notification requirements for each generic device classified. The specific reference language was included when some class I generic devices were first exempted under provisions of the Food and Drug Administration Modernization Act of 1997 (FDAMA). These amendments will provide the same reference for devices that were exempted before that time. The language is intended to conveniently provide the reference, and make the sections clear and easy to read. The status of the devices is not being changed.

DATES: This rule is effective July 25, 2001.

FOR FURTHER INFORMATION CONTACT: Heather S. Rosecrans, Center for Devices and Radiological Health (HFZ-404), 9200 Corporate Blvd., Rockville, MD 20850, 301-594-1190.

SUPPLEMENTARY INFORMATION:

I. Background

Under section 513 of the act (21 U.S.C. 360c), FDA must classify devices into one of three regulatory classes: Class I, class II, or class III. FDA classification of a device is determined by the amount of regulation necessary to provide a reasonable assurance of safety and effectiveness. Under the 1976 amendments (Public Law 94-295), as amended by the SMDA (Public Law 101-629), devices are to be classified into class I (general controls) if there is information showing that the general controls of the act are sufficient to ensure safety and effectiveness; into class II (special controls), if general controls, by themselves, are insufficient

to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide such assurance; and into class III (premarket approval), if there is insufficient information to support classifying a device into class I or class II and the device is a life-sustaining or life-supporting device, or is for a use which is of substantial importance in preventing impairment of human health, or presents a potential unreasonable risk of illness or injury.

Most generic types of devices that were on the market before the date of the 1976 amendments (May 28, 1976) (generally referred to as preamendments devices) have been classified by FDA under the procedures set forth in section 513(c) and (d) of the act through the issuance of classification regulations into one of these three regulatory classes. Devices introduced into interstate commerce for the first time on or after May 28, 1976 (generally referred to as postamendments devices) are classified through the premarket notification process under section 510(k) of the act (21 U.S.C. 360(k)). Section 510(k) of the act and the implementing regulations in 21 CFR part 807 require persons who intend to market a new device to submit a premarket notification report (510(k)) containing information that allows FDA to determine whether the new device is substantially equivalent within the meaning of section 513(i) of the act to a legally marketed device that does not require premarket approval. Unless exempted from premarket notification requirements, persons may not market a new device under section 510(k) of the act, unless they receive a substantial equivalence order from FDA or an order reclassifying the device into class I or class II, under section 513(f) of the act.

On November 21, 1997, the President signed FDAMA into law (Public Law 105-115). Section 206 of FDAMA, in part, added a new section 510(l) to the act. New section 510(l) of the act became effective February 19, 1998. It provides that a class I device is exempt from the premarket notification requirements under section 510(k) of the act, unless the device is intended for a use that is of substantial importance in preventing impairment of human health or it presents a potential unreasonable risk of illness or injury.

To implement this provision, FDA evaluated all class I devices to determine which device types should become exempt under new provision 510(l) of the act and which device types should remain subject to the requirements of 510(k) of the act. FDA

then amended its classification regulations, in part, by publishing in the **Federal Register** of February 2, 1998 (63 FR 5387), a list of certain class I devices that would become exempt from 510(k) requirements on February 19, 1998, subject, however to the limitations found in each classification regulation section (e.g., 21 CFR 862.9, 864.9, etc.), 63 FR 5387, February 2, 1998. The limitations language of each classification states that if a class I or II device is intended for a use different from that of a legally marketed device in that generic type, or if the modified device operates using a different fundamental scientific technology than that of a legally marketed device in that generic type, a new 510(k) submission and clearance is required. The limitations language also lists specific intended uses for in vitro diagnostics devices that would preclude an exemption from the requirements of 510(k). FDA issued a proposed rule in the **Federal Register** of November 12, 1998 (63 FR 63222), to designate class I devices that are exempt from the premarket notification requirements, subject to certain limitations, and to designate class I devices that remain subject to premarket notification requirements under the new statutory criteria. The designations of these devices were codified by a final rule in the **Federal Register** of January 14, 2000 (65 FR 2296).

As published in the January 14, 2000, **Federal Register**, the amendments state, in part, that the limitations in each classification regulation apply to the premarket notification exemptions for each generic device classified in each section. In addition to mentioning the limitations generally in each classification regulation, FDA noted in the **Federal Register** of January 14, 2000, publication that, for clarity and convenience, the classification section for each generic device newly exempted under section 510(l) of the act specifically states that the exemptions are subject to limitations. The agency further noted that for individual device classification sections that had been codified previously as exempt from premarket notification requirements, it would add the same subject-to-limitations language in the future. These amendments now add that language. For example, with this regulation, 21 CFR 862.1190 states that the copper test system "is exempt from the premarket notification procedures in subpart E of part 807 of this chapter *subject to the limitations in § 862.9.*" (Emphasis added.) FDA is adding this specific reference to the limitations for

consistency, clarity, and convenience. The status of the devices is not changing.

This document is published as a final rule with the effective date shown under the **DATES** section above. FDA has already established by regulation that exemptions from premarket notification are subject to certain limitations (e.g., 21 CFR 862.9). This rule merely cross-references, for clarity and convenience, in individual classification regulations the sections that establish these limitations. FDA, therefore, has determined that this final rule has no substantive impact on the public. FDA, therefore, for good cause, finds under 5 U.S.C. 553(b)(3)(B) and (d)(3) that notice and public comment are unnecessary and that this rule may take effect upon publication.

II. Environmental Impact

The agency has determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

III. Analysis of Impacts

FDA has examined the impact of the rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612) (as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Public Law 104–121)), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive order. In addition, this rule is not a significant regulatory action as defined by the Executive order and so is not subject to review under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this rule does not change the status quo for these devices, the agency certifies that this final rule will not have a significant economic impact on a substantial number of small entities. Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires

that agencies prepare a written statement of anticipated costs and benefits before proposing any rule that may result in an expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million in any one year (adjusted annually for inflation). The Unfunded Mandates Reform Act does not require FDA to prepare a statement of costs and benefits for the final rule, because the final rule is not expected to result in any 1-year expenditure that would exceed \$100 million.

IV. Paperwork Reduction Act of 1995

This final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

List of Subjects

21 CFR Parts 862, 866, 868, 870, 872, 874, 876, 878, 880, 882, 884, 888, and 890

Medical devices.

21 CFR Part 864

Biologics, Blood, Laboratories, Medical devices, Packaging and containers.

21 CFR Part 886

Medical devices, Ophthalmic goods and services.

21 CFR Part 892

Medical devices, Radiation protection, X-rays.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 862, 864, 866, 868, 870, 872, 874, 876, 878, 880, 882, 884, 886, 888, 890, and 892 are amended as follows:

PART 862—CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES

1. The authority citation for 21 CFR part 862 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

2. Section 862.1190 is amended by revising paragraph (b) to read as follows:

§ 862.1190 Copper test system.

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(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 862.9.

3. Section 862.1210 is amended by revising paragraph (b) to read as follows:

§ 862.1210 Creatine test system.

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(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 862.9.

4. Section 862.1255 is amended by revising paragraph (b) to read as follows:

§ 862.1255 2,3-Diphosphoglyceric acid test system.

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(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 862.9.

5. Section 862.1290 is amended by revising paragraph (b) to read as follows:

§ 862.1290 Fatty acids test system.

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(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 862.9.

6. Section 862.1305 is amended by revising paragraph (b) to read as follows:

§ 862.1305 Formiminoglutamic acid (FIGLU) test system.

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(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 862.9.

7. Section 862.1320 is amended by revising paragraph (b) to read as follows:

§ 862.1320 Gastric acidity test system.

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(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 862.9.

8. Section 862.1365 is amended by revising paragraph (b) to read as follows:

§ 862.1365 Glutathione test system.

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(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 862.9.

9. Section 862.1380 is amended by revising paragraph (b) to read as follows:

§ 862.1380 Hydroxybutyric dehydrogenase test system.

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(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 862.9.

10. Section 862.1420 is amended by revising paragraph (b) to read as follows:

§ 862.1420 Isocitric dehydrogenase test system.

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(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 862.9.

11. Section 862.1470 is amended by revising paragraph (b) to read as follows:

§ 862.1470 Lipid (total) test system.

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(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 862.9.

12. Section 862.1490 is amended by revising paragraph (b) to read as follows:

§ 862.1490 Lysozyme (muramidase) test system.

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(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 862.9.

13. Section 862.1515 is amended by revising paragraph (b) to read as follows:

§ 862.1515 Nitrogen (amino-nitrogen) test system.

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(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 862.9.

14. Section 862.1565 is amended by revising paragraph (b) to read as follows:

§ 862.1565 6-Phosphogluconate dehydrogenase test system.

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(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 862.9.

15. Section 862.1575 is amended by revising paragraph (b) to read as follows:

§ 862.1575 Phospholipid test system.

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(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 862.9.

16. Section 862.1640 is amended by revising paragraph (b) to read as follows:

§ 862.1640 Protein-bound iodine test system.

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(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 862.9.

17. Section 862.1670 is amended by revising paragraph (b) to read as follows:

§ 862.1670 Sorbitol dehydrogenase test system.

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(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 862.9.

18. Section 862.1720 is amended by revising paragraph (b) to read as follows:

§ 862.1720 Triose phosphate isomerase test system.

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(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 subject to the limitations in § 862.9.

19. Section 862.1815 is amended by revising paragraph (b) to read as follows:

§ 862.1815 Vitamin E test system.

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(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 subject to the limitations in § 862.9.

20. Section 862.2050 is amended by revising paragraph (b) to read as follows:

§ 862.2050 General purpose laboratory equipment labeled or promoted for a specific medical use.

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(b) *Classification*. Class I (general controls). The device is identified in paragraph (a) of this section and is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 862.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

21. Section 862.2100 is amended by revising paragraph (b) to read as follows:

§ 862.2100 Calculator/data processing module for clinical use.

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(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 862.9.

22. Section 862.2230 is amended by revising paragraph (b) to read as follows:

§ 862.2230 Chromatographic separation material for clinical use.

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(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 862.9.

23. Section 862.2310 is amended by revising paragraph (b) to read as follows:

§ 862.2310 Clinical sample concentrator.

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(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 862.9.

24. Section 862.2320 is amended by revising paragraph (b) to read as follows:

§ 862.2320 Beta or gamma counter for clinical use.

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(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 862.9.

25. Section 862.2485 is amended by revising paragraph (b) to read as follows:

§ 862.2485 Electrophoresis apparatus for clinical use.

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(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 862.9.

26. Section 862.2720 is amended by revising paragraph (b) to read as follows:

§ 862.2720 Plasma oncometer for clinical use.

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(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 862.9.

27. Section 862.2800 is amended by revising paragraph (b) to read as follows:

§ 862.2800 Refractometer for clinical use.

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(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 862.9.

28. Section 862.2920 is amended by revising paragraph (b) to read as follows:

§ 862.2920 Plasma viscometer for clinical use.

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(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in

subpart E of part 807 of this chapter subject to the limitations in § 862.9.

PART 864—HEMATOLOGY AND PATHOLOGY DEVICES

29. The authority citation for 21 CFR part 864 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

30. Section 864.1850 is amended by revising paragraph (b) to read as follows:

§ 864.1850 Dye and chemical solution stains.

(b) *Classification.* Class I (general controls). These devices are exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 864.9. These devices are also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

31. Section 864.2220 is amended by revising paragraph (b) to read as follows:

§ 864.2220 Synthetic cell and tissue culture media and components.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 864.9.

32. Section 864.2240 is amended by revising paragraph (b) to read as follows:

§ 864.2240 Cell and tissue culture supplies and equipment.

(b) *Classification.* Class I (general controls). These devices are exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 864.9. If the devices are not labeled or otherwise represented as sterile, they are exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

33. Section 864.2260 is amended by revising paragraph (b) to read as follows:

§ 864.2260 Chromosome culture kit.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 864.9.

34. Section 864.2360 is amended by revising paragraph (b) to read as follows:

§ 864.2360 Mycoplasma detection media and components.

(b) *Classification.* Class I (general controls). These devices are exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 864.9.

35. Section 864.2800 is amended by revising paragraph (b) to read as follows:

§ 864.2800 Animal and human sera.

(b) *Classification.* Class I (general controls). These devices are exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 864.9.

36. Section 864.2875 is amended by revising paragraph (b) to read as follows:

§ 864.2875 Balanced salt solutions or formulations.

(b) *Classification.* Class I (general controls). These devices are exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 864.9.

37. Section 864.3010 is amended by revising paragraph (b) to read as follows:

§ 864.3010 Tissue processing equipment.

(b) *Classification.* Class I (general controls). These devices are exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 864.9. The devices are also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

38. Section 864.3300 is amended by revising paragraph (b) to read as follows:

§ 864.3300 Cytocentrifuge.

(b) *Classification.* Class I (general controls). This device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 864.9.

39. Section 864.3400 is amended by revising paragraph (b) to read as follows:

§ 864.3400 Device for sealing microsections.

(b) *Classification.* Class I (general controls). This device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 864.9.

40. Section 864.3600 is amended by revising paragraph (b) to read as follows:

§ 864.3600 Microscopes and accessories.

(b) *Classification.* Class I (general controls). These devices are exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 864.9. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

41. Section 864.3800 is amended by revising paragraph (b) to read as follows:

§ 864.3800 Automated slide stainer.

(b) *Classification.* Class I (general controls). This device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 864.9.

42. Section 864.3875 is amended by revising paragraph (b) to read as follows:

§ 864.3875 Automated tissue processor.

(b) *Classification.* Class I (general controls). This device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 864.9.

43. Section 864.4010 is amended by revising paragraph (b) to read as follows:

§ 864.4010 General purpose reagent.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 864.9. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

44. Section 864.4400 is amended by revising paragraph (b) to read as follows:

§ 864.4400 Enzyme preparations.

(b) *Classification.* Class I (general controls). This device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 864.9.

45. Section 864.5350 is amended by revising paragraph (b) to read as follows:

§ 864.5350 Microsedimentation centrifuge.

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(b) *Classification.* Class I (general controls). This device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 864.9.

46. Section 864.5800 is amended by revising paragraph (b) to read as follows:

§ 864.5800 Automated sedimentation rate device.

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(b) *Classification.* Class I (general controls). This device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 864.9.

47. Section 864.5850 is amended by revising paragraph (b) to read as follows:

§ 864.5850 Automated slide spinner.

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(b) *Classification.* Class I (general controls). This device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 864.9.

48. Section 864.6160 is amended by revising paragraph (b) to read as follows:

§ 864.6160 Manual blood cell counting device.

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(b) *Classification.* Class I (general controls). This device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 864.9.

49. Section 864.6600 is amended by revising paragraph (b) to read as follows:

§ 864.6600 Osmotic fragility test.

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(b) *Classification.* Class I (general controls). This device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 864.9.

50. Section 864.6700 is amended by revising paragraph (b) to read as follows:

§ 864.6700 Erythrocyte sedimentation rate test.

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(b) *Classification.* Class I (general controls). This device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 864.9.

51. Section 864.7660 is amended by revising paragraph (b) to read as follows:

§ 864.7660 Leukocyte alkaline phosphatase test.

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(b) *Classification.* Class I (general controls). This device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 864.9.

52. Section 864.7675 is amended by revising paragraph (b) to read as follows:

§ 864.7675 Leukocyte peroxidase test.

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(b) *Classification.* Class I (general controls). This device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 864.9.

53. Section 864.7900 is amended by revising paragraph (b) to read as follows:

§ 864.7900 Thromboplastin generation test.

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(b) *Classification.* Class I (general controls). This device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 864.9.

54. Section 864.8200 is amended by revising paragraph (b) to read as follows:

§ 864.8200 Blood cell diluent.

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(b) *Classification.* Class I (general controls). This device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 864.9.

55. Section 864.8500 is amended by revising paragraph (b) to read as follows:

§ 864.8500 Lymphocyte separation medium.

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(b) *Classification.* Class I (general controls). This device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 864.9.

56. Section 864.8540 is amended by revising paragraph (b) to read as follows:

§ 864.8540 Red cell lysing reagent.

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(b) *Classification.* Class I (general controls). This device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 864.9.

PART 866—IMMUNOLOGY AND MICROBIOLOGY DEVICES

57. The authority citation for 21 CFR part 866 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

58. Section 866.2050 is amended by revising paragraph (b) to read as follows:

§ 866.2050 Staphylococcal typing bacteriophage.

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(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9.

59. Section 866.2120 is amended by revising paragraph (b) to read as follows:

§ 866.2120 Anaerobic chamber.

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(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9. The device is also exempt from the good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

60. Section 866.2160 is amended by revising paragraph (b) to read as follows:

§ 866.2160 Coagulase plasma.

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(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9.

61. Section 866.2170 is amended by revising paragraph (b) to read as follows:

§ 866.2170 Automated colony counter.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9.

62. Section 866.2180 is amended by revising paragraph (b) to read as follows:

§ 866.2180 Manual colony counter.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9. The device is also exempt from the good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

63. Section 866.2300 is amended by revising paragraph (b) to read as follows:

§ 866.2300 Multipurpose culture medium.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9.

64. Section 866.2320 is amended by revising paragraph (b) to read as follows:

§ 866.2320 Differential culture medium.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9.

65. Section 866.2330 is amended by revising paragraph (b) to read as follows:

§ 866.2330 Enriched culture medium.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9.

66. Section 866.2350 is amended by revising paragraph (b) to read as follows:

§ 866.2350 Microbiological assay culture medium.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9.

67. Section 866.2360 is amended by revising paragraph (b) to read as follows:

§ 866.2360 Selective culture medium.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9.

68. Section 866.2440 is amended by revising paragraph (b) to read as follows:

§ 866.2440 Automated medium dispensing and stacking device.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9. The device is also exempt from the good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

69. Section 866.2450 is amended by revising paragraph (b) to read as follows:

§ 866.2450 Supplement for culture media.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9.

70. Section 866.2480 is amended by revising paragraph (b) to read as follows:

§ 866.2480 Quality control kit for culture media.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9.

71. Section 866.2500 is amended by revising paragraph (b) to read as follows:

§ 866.2500 Microtiter diluting and dispensing device.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9.

72. Section 866.2540 is amended by revising paragraph (b) to read as follows:

§ 866.2540 Microbiological incubator.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9. The device is also exempt from the good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

73. Section 866.2580 is amended by revising paragraph (b) to read as follows:

§ 866.2580 Gas-generating device.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9.

74. Section 866.2600 is amended by revising paragraph (b) to read as follows:

§ 866.2600 Wood's fluorescent lamp.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9. The device is also exempt from the good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

75. Section 866.3010 is amended by revising paragraph (b) to read as follows:

§ 866.3010 Acinetobacter calcoaceticus serological reagents.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in

subpart E of part 807 of this chapter subject to the limitations in § 866.9.

76. Section 866.3020 is amended by revising paragraph (b) to read as follows:

§ 866.3020 Adenovirus serological reagents.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9.

77. Section 866.3035 is amended by revising paragraph (b) to read as follows:

§ 866.3035 Arizona spp. serological reagents.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9.

78. Section 866.3065 is amended by revising paragraph (b) to read as follows:

§ 866.3065 Bordetella spp. serological reagents.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9.

79. Section 866.3125 is amended by revising paragraph (b) to read as follows:

§ 866.3125 Citrobacter spp. serological reagents.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9.

80. Section 866.3205 is amended by revising paragraph (b) to read as follows:

§ 866.3205 Echovirus serological reagents.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9.

81. Section 866.3250 is amended by revising paragraph (b) to read as follows:

§ 866.3250 Erysipelothrix rhusiopathiae serological reagents.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9.

82. Section 866.3255 is amended by revising paragraph (b) to read as follows:

§ 866.3255 Escherichia coli serological reagents.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9.

83. Section 866.3270 is amended by revising paragraph (b) to read as follows:

§ 866.3270 Flavobacterium spp. serological reagents.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9.

84. Section 866.3330 is amended by revising paragraph (b) to read as follows:

§ 866.3330 Influenza virus serological reagents.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9.

85. Section 866.3340 is amended by revising paragraph (b) to read as follows:

§ 866.3340 Klebsiella spp. serological reagents.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9.

86. Section 866.3400 is amended by revising paragraph (b) to read as follows:

§ 866.3400 Parainfluenza virus serological reagents.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9.

87. Section 866.3410 is amended by revising paragraph (b) to read as follows:

§ 866.3410 Proteus spp. (Weil-Felix) serological reagents.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9.

88. Section 866.3470 is amended by revising paragraph (b) to read as follows:

§ 866.3470 Reovirus serological reagents.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the

premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9.

89. Section 866.3490 is amended by revising paragraph (b) to read as follows:

§ 866.3490 Rhinovirus serological reagents.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9.

90. Section 866.3520 is amended by revising paragraph (b) to read as follows:

§ 866.3520 Rubeola (measles) virus serological reagents.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9.

91. Section 866.3630 is amended by revising paragraph (b) to read as follows:

§ 866.3630 Serratia spp. serological reagents.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9.

92. Section 866.3700 is amended by revising paragraph (b) to read as follows:

§ 866.3700 Staphylococcus aureus serological reagents.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9.

93. Section 866.3720 is amended by revising paragraph (b) to read as follows:

§ 866.3720 Streptococcus spp. exoenzyme reagents.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9.

94. Section 866.4100 is amended by revising paragraph (b) to read as follows:

§ 866.4100 Complement reagent.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9.

95. Section 866.4500 is amended by revising paragraph (b) to read as follows:

§ 866.4500 Immunoelectrophoresis equipment.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9.

96. Section 866.4520 is amended by revising paragraph (b) to read as follows:

§ 866.4520 Immunofluorometer equipment.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9.

97. Section 866.4540 is amended by revising paragraph (b) to read as follows:

§ 866.4540 Immunonephelometer equipment.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9.

98. Section 866.4600 is amended by revising paragraph (b) to read as follows:

§ 866.4600 Ouchterlony agar plate.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9.

99. Section 866.4800 is amended by revising paragraph (b) to read as follows:

§ 866.4800 Radial immunodiffusion plate.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9.

100. Section 866.4830 is amended by revising paragraph (b) to read as follows:

§ 866.4830 Rocket immunoelectrophoresis equipment.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9.

101. Section 866.4900 is amended by revising paragraph (b) to read as follows:

§ 866.4900 Support gel.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9.

102. Section 866.5170 is amended by revising paragraph (b) to read as follows:

§ 866.5170 Breast milk immunological test system.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9.

103. Section 866.5220 is amended by revising paragraph (b) to read as follows:

§ 866.5220 Cohn fraction II immunological test system.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9.

104. Section 866.5230 is amended by revising paragraph (b) to read as follows:

§ 866.5230 Colostrum immunological test system.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9.

105. Section 866.5360 is amended by revising paragraph (b) to read as follows:

§ 866.5360 Cohn fraction IV immunological test system.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9.

106. Section 866.5370 is amended by revising paragraph (b) to read as follows:

§ 866.5370 Cohn fraction V immunological test system.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9.

107. Section 866.5520 is amended by revising paragraph (b) to read as follows:

§ 866.5520 Immunoglobulin G (Fab fragment specific) immunological test system.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9.

108. Section 866.5530 is amended by revising paragraph (b) to read as follows:

§ 866.5530 Immunoglobulin G (Fc fragment specific) immunological test system.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9.

109. Section 866.5540 is amended by revising paragraph (b) to read as follows:

§ 866.5540 Immunoglobulin G (Fd fragment specific) immunological test system.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9.

110. Section 866.5700 is amended by revising paragraph (b) to read as follows:

§ 866.5700 Whole human plasma or serum immunological test system.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9.

111. Section 866.5800 is amended by revising paragraph (b) to read as follows:

§ 866.5800 Seminal fluid (sperm) immunological test system.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9.

112. Section 866.5860 is amended by revising paragraph (b) to read as follows:

§ 866.5860 Total spinal fluid immunological test system.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9.

PART 868—ANESTHESIOLOGY DEVICES

113. The authority citation for 21 CFR part 868 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

114. Section 868.1030 is amended by revising paragraph (b) to read as follows:

§ 868.1030 Manual algometer.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter

subject to the limitations in § 868.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

115. Section 868.1100 is amended by revising paragraph (b) to read as follows:

§ 868.1100 Arterial blood sampling kit.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9.

116. Section 868.1575 is amended by revising paragraph (b) to read as follows:

§ 868.1575 Gas collection vessel.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9.

117. Section 868.1870 is amended by revising paragraph (b) to read as follows:

§ 868.1870 Gas volume calibrator.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9.

118. Section 868.1930 is amended by revising paragraph (b) to read as follows:

§ 868.1930 Stethoscope head.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9.

119. Section 868.1965 is amended by revising paragraph (b) to read as follows:

§ 868.1965 Switching valve (ploss).

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

120. Section 868.1975 is amended by revising paragraph (b) to read as follows:

§ 868.1975 Water vapor analyzer.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9.

121. Section 868.2300 is amended by revising paragraph (b) to read as follows:

§ 868.2300 Bourdon gauge flowmeter.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9.

122. Section 868.2320 is amended by revising paragraph (b) to read as follows:

§ 868.2320 Uncompensated thorpe tube flowmeter.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9.

123. Section 868.2340 is amended by revising paragraph (b) to read as follows:

§ 868.2340 Compensated thorpe tube flowmeter.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9.

124. Section 868.2350 is amended by revising paragraph (b) to read as follows:

§ 868.2350 Gas calibration flowmeter.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9.

125. Section 868.2610 is amended by revising paragraph (b) to read as follows:

§ 868.2610 Gas pressure gauge.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9.

126. Section 868.2620 is amended by revising paragraph (b) to read as follows:

§ 868.2620 Gas pressure calibrator.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9.

127. Section 868.2700 is amended by revising paragraph (b) to read as follows:

§ 868.2700 Pressure regulator.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9.

128. Section 868.2875 is amended by revising paragraph (b) to read as follows:

§ 868.2875 Differential pressure transducer.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9.

129. Section 868.2885 is amended by revising paragraph (b) to read as follows:

§ 868.2885 Gas flow transducer.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9.

130. Section 868.5100 is amended by revising paragraph (b) to read as follows:

§ 868.5100 Nasopharyngeal airway.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9.

131. Section 868.5110 is amended by revising paragraph (b) to read as follows:

§ 868.5110 Oropharyngeal airway.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9.

132. Section 868.5220 is amended by revising paragraph (b) to read as follows:

§ 868.5220 Blow bottle.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

133. Section 868.5240 is amended by revising paragraph (b) to read as follows:

§ 868.5240 Anesthesia breathing circuit.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9.

134. Section 868.5280 is amended by revising paragraph (b) to read as follows:

§ 868.5280 Breathing tube support.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9.

135. Section 868.5300 is amended by revising paragraph (b) to read as follows:

§ 868.5300 Carbon dioxide absorbent.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9.

136. Section 868.5310 is amended by revising paragraph (b) to read as follows:

§ 868.5310 Carbon dioxide absorber.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9.

137. Section 868.5320 is amended by revising paragraph (b) to read as follows:

§ 868.5320 Reservoir bag.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9.

138. Section 868.5340 is amended by revising paragraph (b) to read as follows:

§ 868.5340 Nasal oxygen cannula.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9.

139. Section 868.5350 is amended by revising paragraph (b) to read as follows:

§ 868.5350 Nasal oxygen catheter.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9.

140. Section 868.5365 is amended by revising paragraph (b) to read as follows:

§ 868.5365 Posture chair for cardiac or pulmonary treatment.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9.

141. Section 868.5375 is amended by revising paragraph (b) to read as follows:

§ 868.5375 Heat and moisture condensor (artificial nose).

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9.

142. Section 868.5420 is amended by revising paragraph (b) to read as follows:

§ 868.5420 Ether hook.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

143. Section 868.5460 is amended by revising paragraph (b) to read as follows:

§ 868.5460 Therapeutic humidifier for home use.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9.

144. Section 868.5530 is amended by revising paragraph (b) to read as follows:

§ 868.5530 Flexible laryngoscope.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9.

145. Section 868.5540 is amended by revising paragraph (b) to read as follows:

§ 868.5540 Rigid laryngoscope.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9.

146. Section 868.5550 is amended by revising paragraph (b) to read as follows:

§ 868.5550 Anesthetic gas mask.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9.

147. Section 868.5560 is amended by revising paragraph (b) to read as follows:

§ 868.5560 Gas mask head strap.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9.

148. Section 868.5570 is amended by revising paragraph (b) to read as follows:

§ 868.5570 Nonbreathing mask.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9.

149. Section 868.5580 is amended by revising paragraph (b) to read as follows:

§ 868.5580 Oxygen mask.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9.

150. Section 868.5590 is amended by revising paragraph (b) to read as follows:

§ 868.5590 Scavenging mask.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9.

151. Section 868.5600 is amended by revising paragraph (b) to read as follows:

§ 868.5600 Venturi mask.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9.

152. Section 868.5760 is amended by revising paragraph (b) to read as follows:

§ 868.5760 Cuff spreader.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with

respect to general requirements concerning records, and § 820.198, with respect to complaint files.

153. Section 868.5770 is amended by revising paragraph (b) to read as follows:

§ 868.5770 Tracheal tube fixation device.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9.

154. Section 868.5780 is amended by revising paragraph (b) to read as follows:

§ 868.5780 Tube introduction forceps.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9.

155. Section 868.5790 is amended by revising paragraph (b) to read as follows:

§ 868.5790 Tracheal tube stylet.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9.

156. Section 868.5795 is amended by revising paragraph (b) to read as follows:

§ 868.5795 Tracheal tube cleaning brush.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

157. Section 868.5810 is amended by revising paragraph (b) to read as follows:

§ 868.5810 Airway connector.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9.

158. Section 868.5820 is amended by revising paragraph (b) to read as follows:

§ 868.5820 Dental protector.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9.

159. Section 868.5860 is amended by revising paragraph (b) to read as follows:

§ 868.5860 Pressure tubing and accessories.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9.

160. Section 868.5975 is amended by revising paragraph (b) to read as follows:

§ 868.5975 Ventilator tubing.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9.

161. Section 868.5995 is amended by revising paragraph (b) to read as follows:

§ 868.5995 Tee drain (water trap).

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9.

162. Section 868.6100 is amended by revising paragraph (b) to read as follows:

§ 868.6100 Anesthetic cabinet, table, or tray.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9.

163. Section 868.6175 is amended by revising paragraph (b) to read as follows:

§ 868.6175 Cardiopulmonary emergency cart.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

164. Section 868.6225 is amended by revising paragraph (b) to read as follows:

§ 868.6225 Nose clip.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9. The

device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

165. Section 868.6400 is amended by revising paragraph (b) to read as follows:

§ 868.6400 Calibration gas.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9.

166. Section 868.6700 is amended by revising paragraph (b) to read as follows:

§ 868.6700 Anesthesia stool.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9.

167. Section 868.6820 is amended by revising paragraph (b) to read as follows:

§ 868.6820 Patient position support.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9.

168. Section 868.6885 is amended by revising paragraph (b) to read as follows:

§ 868.6885 Medical gas yoke assembly.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9.

PART 870—CARDIOVASCULAR DEVICES

169. The authority citation for 21 CFR part 870 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

170. Section 870.1875 is amended by revising paragraph (a)(2) to read as follows:

§ 870.1875 Stethoscope.

(a) * * *

(2) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 870.9.

* * * * *

171. Section 870.2390 is amended by revising paragraph (b) to read as follows:

§ 870.2390 Phonocardiograph.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 870.9.

172. Section 870.2600 is amended by revising paragraph (b) to read as follows:

§ 870.2600 Signal isolation system.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 870.9.

173. Section 870.2620 is amended by revising paragraph (b) to read as follows:

§ 870.2620 Line isolation monitor.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 870.9.

174. Section 870.2640 is amended by revising paragraph (b) to read as follows:

§ 870.2640 Portable leakage current alarm.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 870.9.

175. Section 870.2810 is amended by revising paragraph (b) to read as follows:

§ 870.2810 Paper chart recorder.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 870.9.

176. Section 870.3650 is amended by revising paragraph (b) to read as follows:

§ 870.3650 Pacemaker polymeric mesh bag.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 870.9.

177. Section 870.3670 is amended by revising paragraph (b) to read as follows:

§ 870.3670 Pacemaker charger.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 870.9.

178. Section 870.3690 is amended by revising paragraph (b) to read as follows:

§ 870.3690 Pacemaker test magnet.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 870.9.

179. Section 870.3730 is amended by revising paragraph (b) to read as follows:

§ 870.3730 Pacemaker service tools.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 870.9.

180. Section 870.3945 is amended by revising paragraph (b) to read as follows:

§ 870.3945 Prosthetic heart valve sizer.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 870.9.

181. Section 870.4500 is amended by revising paragraph (b) to read as follows:

§ 870.4500 Cardiovascular surgical instruments.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 870.9.

PART 872—DENTAL DEVICES

182. The authority citation for 21 CFR part 872 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

183. Section 872.1500 is amended by revising paragraph (b) to read as follows:

§ 872.1500 Gingival fluid measurer.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9.

184. Section 872.1730 is amended by revising paragraph (b) to read as follows:

§ 872.1730 Electrode gel for pulp testers.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9.

185. Section 872.1820 is amended by revising paragraph (b) to read as follows:

§ 872.1820 Dental x-ray exposure alignment device.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9.

186. Section 872.1840 is amended by revising paragraph (b) to read as follows:

§ 872.1840 Dental x-ray position indicating device.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9.

187. Section 872.1850 is amended by revising paragraph (b) to read as follows:

§ 872.1850 Lead-lined position indicator.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9.

188. Section 872.1905 is amended by revising paragraph (b) to read as follows:

§ 872.1905 Dental x-ray film holder.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9. If the device is not labeled or otherwise represented as sterile, it is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exceptions of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

189. Section 872.3080 is amended by revising paragraph (b) to read as follows:

§ 872.3080 Mercury and alloy dispenser.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9.

190. Section 872.3100 is amended by revising paragraph (b) to read as follows:

§ 872.3100 Dental amalgamator.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9.

191. Section 872.3110 is amended by revising paragraph (b) to read as follows:

§ 872.3110 Dental amalgam capsule.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9.

192. Section 872.3130 is amended by revising paragraph (b) to read as follows:

§ 872.3130 Preformed anchor.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9.

193. Section 872.3140 is amended by revising paragraph (b) to read as follows:

§ 872.3140 Resin applicator.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9. If the device is not labeled or otherwise represented as sterile, the device is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exceptions of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

194. Section 872.3150 is amended by revising paragraph (b) to read as follows:

§ 872.3150 Articulator.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9. If the device is not labeled or otherwise represented as sterile, the device is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exceptions of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

195. Section 872.3165 is amended by revising paragraph (b) to read as follows:

§ 872.3165 Precision attachment.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9.

196. Section 872.3220 is amended by revising paragraph (b) to read as follows:

§ 872.3220 Facebow.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the

premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9. If the device is not labeled or otherwise represented as sterile, the device is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exceptions of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

197. Section 872.3240 is amended by revising paragraph (b) to read as follows:

§ 872.3240 Dental bur.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9.

198. Section 872.3285 is amended by revising paragraph (b) to read as follows:

§ 872.3285 Preformed clasp.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9.

199. Section 872.3330 is amended by revising paragraph (b) to read as follows:

§ 872.3330 Preformed crown.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9.

200. Section 872.3350 is amended by revising paragraph (b) to read as follows:

§ 872.3350 Gold or stainless steel cusp.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9.

201. Section 872.3360 is amended by revising paragraph (b) to read as follows:

§ 872.3360 Preformed cusp.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9.

202. Section 872.3410 is amended by revising paragraph (b) to read as follows:

§ 872.3410 Ethylene oxide homopolymer and/or carboxymethylcellulose sodium denture adhesive.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the

premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9.

203. Section 872.3490 is amended by revising paragraph (b) to read as follows:

§ 872.3490 Carboxymethylcellulose sodium and/or polyvinylmethylether maleic acid calcium-sodium double salt denture adhesive.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9.

204. Section 872.3520 is amended by revising paragraph (b) to read as follows:

§ 872.3520 OTC denture cleanser.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9.

205. Section 872.3530 is amended by revising paragraph (b) to read as follows:

§ 872.3530 Mechanical denture cleaner.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9.

206. Section 872.3580 is amended by revising paragraph (b) to read as follows:

§ 872.3580 Preformed gold denture tooth.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9.

207. Section 872.3670 is amended by revising paragraph (b) to read as follows:

§ 872.3670 Resin impression tray material.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

208. Section 872.3730 is amended by revising paragraph (b) to read as follows:

§ 872.3730 Pantograph.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the

premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

209. Section 872.3740 is amended by revising paragraph (b) to read as follows:

§ 872.3740 Retentive and splinting pin.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9.

210. Section 872.3810 is amended by revising paragraph (b) to read as follows:

§ 872.3810 Root canal post.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9.

211. Section 872.3830 is amended by revising paragraph (b) to read as follows:

§ 872.3830 Endodontic paper point.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9.

212. Section 872.3840 is amended by revising paragraph (b) to read as follows:

§ 872.3840 Endodontic silver point.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9.

213. Section 872.3850 is amended by revising paragraph (b) to read as follows:

§ 872.3850 Gutta percha.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9.

214. Section 872.3900 is amended by revising paragraph (b) to read as follows:

§ 872.3900 Posterior artificial tooth with a metal insert.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in

subpart E of part 807 of this chapter subject to the limitations in § 872.9.

215. Section 872.3910 is amended by revising paragraph (b) to read as follows:

§ 872.3910 Backing and facing for an artificial tooth.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9.

216. Section 872.4130 is amended by revising paragraph (b) to read as follows:

§ 872.4130 Intraoral dental drill.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9.

217. Section 872.4565 is amended by revising paragraph (b) to read as follows:

§ 872.4565 Dental hand instrument.

* * * * *

(b) *Classification.* Class I (general controls). If the device is made of the same materials that were used in the device before May 28, 1976, it is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9.

218. Section 872.4620 is amended by revising paragraph (b) to read as follows:

§ 872.4620 Fiber optic dental light.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9.

219. Section 872.4630 is amended by revising paragraph (b) to read as follows:

§ 872.4630 Dental operating light.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9.

220. Section 872.4730 is amended by revising paragraph (b) to read as follows:

§ 872.4730 Dental injecting needle.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9.

221. Section 872.5410 is amended by revising paragraph (b) to read as follows:

§ 872.5410 Orthodontic appliance and accessories.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9.

222. Section 872.5525 is amended by revising paragraph (b) to read as follows:

§ 872.5525 Preformed tooth positioner.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9.

223. Section 872.6010 is amended by revising paragraph (b) to read as follows:

§ 872.6010 Abrasive device and accessories.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

224. Section 872.6030 is amended by revising paragraph (b) to read as follows:

§ 872.6030 Oral cavity abrasive polishing agent.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9.

225. Section 872.6050 is amended by revising paragraph (b) to read as follows:

§ 872.6050 Saliva absorber.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

226. Section 872.6100 is amended by revising paragraph (b) to read as follows:

§ 872.6100 Anesthetic warmer.

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(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9.

227. Section 872.6140 is amended by revising paragraph (b) to read as follows:

§ 872.6140 Articulation paper.

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(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

228. Section 872.6200 is amended by revising paragraph (b) to read as follows:

§ 872.6200 Base plate shellac.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

229. Section 872.6290 is amended by revising paragraph (b) to read as follows:

§ 872.6290 Prophylaxis cup.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

230. Section 872.6475 is amended by revising paragraph (b) to read as follows:

§ 872.6475 Heat source for bleaching teeth.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in

subpart E of part 807 of this chapter subject to the limitations in § 872.9.

231. Section 872.6510 is amended by revising paragraph (b) to read as follows:

§ 872.6510 Oral irrigation unit.

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(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9.

232. Section 872.6570 is amended by revising paragraph (b) to read as follows:

§ 872.6570 Impression tube.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

233. Section 872.6650 is amended by revising paragraph (b) to read as follows:

§ 872.6650 Massaging pick or tip for oral hygiene.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

234. Section 872.6670 is amended by revising paragraph (b) to read as follows:

§ 872.6670 Silicate protector.

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(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

235. Section 872.6710 is amended by revising paragraph (b) to read as follows:

§ 872.6710 Boiling water sterilizer.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9.

236. Section 872.6855 is amended by revising paragraph (b) to read as follows:

§ 872.6855 Manual toothbrush.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

237. Section 872.6865 is amended by revising paragraph (b) to read as follows:

§ 872.6865 Powered toothbrush.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9.

238. Section 872.6870 is amended by revising paragraph (b) to read as follows:

§ 872.6870 Disposable fluoride tray.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

239. Section 872.6880 is amended by revising paragraph (b) to read as follows:

§ 872.6880 Preformed impression tray.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements

concerning records, and § 820.198, with respect to complaint files.

240. Section 872.6890 is amended by revising paragraph (b) to read as follows:

§ 872.6890 Intraoral dental wax.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

PART 874—EAR, NOSE, AND THROAT DEVICES

241. The authority citation for 21 CFR part 874 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

242. Section 874.1060 is amended by revising paragraph (b) to read as follows:

§ 874.1060 Acoustic chamber for audiometric testing.

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(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 874.9.

243. Section 874.1080 is amended by revising paragraph (b) to read as follows:

§ 874.1080 Audiometer calibration set.

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(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 874.9.

244. Section 874.3375 is amended by revising paragraph (b) to read as follows:

§ 874.3375 Battery-powered artificial larynx.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 874.9.

245. Section 874.4140 is amended by revising paragraph (b) to read as follows:

§ 874.4140 Ear, nose, and throat bur.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 874.9.

246. Section 874.4175 is amended by revising paragraph (b) to read as follows:

§ 874.4175 Nasopharyngeal catheter.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 874.9.

247. Section 874.4350 is amended by revising paragraph (b) to read as follows:

§ 874.4350 Ear, nose, and throat fiberoptic light source and carrier.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 874.9.

248. Section 874.4750 is amended by revising paragraph (b) to read as follows:

§ 874.4750 Laryngostroboscope.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 874.9.

249. Section 874.4770 is amended by revising paragraph (b) to read as follows:

§ 874.4770 Otoscope.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 874.9 only when used in the external ear canal.

250. Section 874.5220 is amended by revising paragraph (b) to read as follows:

§ 874.5220 Ear, nose, and throat drug administration device.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 874.9. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

251. Section 874.5800 is amended by revising paragraph (b) to read as follows:

§ 874.5800 External nasal splint.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 874.9.

PART 876—GASTROENTEROLOGY—UROLOGY DEVICES

252. The authority citation for 21 CFR part 876 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

253. Section 876.1075 is amended by revising paragraph (b)(2) to read as follows:

§ 876.1075 Gastroenterology-urology biopsy instrument.

(2) Class I for the biopsy forceps cover and the non-electric biopsy forceps. The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 876.9.

254. Section 876.1500 is amended by revising paragraph (b)(2) to read as follows:

§ 876.1500 Endoscope and accessories.

(2) Class I for the photographic accessories for endoscope, miscellaneous bulb adapter for endoscope, binocular attachment for endoscope, eyepiece attachment for prescription lens, teaching attachment, inflation bulb, measuring device for panendoscope, photographic equipment for physiologic function monitor, special lens instrument for endoscope, smoke removal tube, rechargeable battery box, pocket battery box, bite block for endoscope, and cleaning brush for endoscope. The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 876.9.

255. Section 876.4530 is amended by revising paragraph (b) to read as follows:

§ 876.4530 Gastroenterology-urology fiberoptic retractor.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 876.9.

256. Section 876.4560 is amended by revising paragraph (b) to read as follows:

§ 876.4560 Ribdam.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 876.9.

257. Section 876.4590 is amended by revising paragraph (b) to read as follows:

§ 876.4590 Interlocking urethral sound.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 876.9.

258. Section 876.4730 is amended by revising paragraph (b) to read as follows:

§ 876.4730 Manual gastroenterology-urology surgical instrument and accessories.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 876.9.

259. Section 876.4890 is amended by revising paragraph (b)(2) to read as follows:

§ 876.4890 Urological table and accessories.

(2) Class I for the manually powered table and accessories, and for stirrups for electrically powered table. The device subject to this paragraph (b)(2) is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 876.9.

260. Section 876.5030 is amended by revising paragraph (b) to read as follows:

§ 876.5030 Continent ileostomy catheter.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 876.9.

261. Section 876.5090 is amended by revising paragraph (b)(2) to read as follows:

§ 876.5090 Supra' urological catheter and accessories.

(2) Class I for the catheter punch instrument, nondisposable cannula and trocar, and gastro-urological trocar. The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 876.9.

262. Section 876.5130 is amended by revising paragraph (b)(2) to read as follows:

§ 876.5130 Urological catheter and accessories.

(2) Class I for the ureteral stylet (guidewire), stylet for gastrourological

catheter, ureteral catheter adapter, ureteral catheter connector, and ureteral catheter holder. The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 876.9.

263. Section 876.5250 is amended by revising paragraph (b)(2) to read as follows:

§ 876.5250 Urine collector and accessories.

* * * * *

(b) * * *

(2) Class I (general controls). For a urine collector and accessories not intended to be connected to an indwelling catheter, subject to the limitations in § 876.9. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

264. Section 876.5450 is amended by revising paragraph (b) to read as follows:

§ 876.5450 Rectal dilator.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 876.9.

265. Section 876.5520 is amended by revising paragraph (b)(2) to read as follows:

§ 876.5520 Urethral dilator.

* * * * *

(b) * * *

(2) Class I for the urethrometer, urological bougie, filiform and filiform follower, and metal or plastic urethral sound. The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 876.9.

266. Section 876.5540 is amended by revising paragraph (b)(4) to read as follows:

§ 876.5540 Blood access device and accessories.

* * * * *

(b) * * *

(4) Class I for the cannula clamp, disconnect forceps, crimp plier, tube plier, crimp ring, and joint ring, accessories for both the implanted and nonimplanted blood access device. The devices subject to this paragraph (b)(4) are exempt from the premarket notification procedures in subpart E of

part 807 of this chapter subject to the limitations in § 876.9.

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267. Section 876.5820 is amended by revising paragraph (b)(2) to read as follows:

§ 876.5820 Hemodialysis system and accessories.

* * * * *

(b) * * *

(2) Class I for other accessories of the hemodialysis system remote from the extracorporeal blood system and the dialysate delivery system, such as the unpowered dialysis chair, hemodialysis start/stop tray, dialyzer holder set, and dialysis tie gun and ties. The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 876.9.

268. Section 876.5900 is amended by revising paragraph (b) to read as follows:

§ 876.5900 Ostomy pouch and accessories.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 876.9.

269. Section 876.5920 is amended by revising paragraph (b) to read as follows:

§ 876.5920 Protective garment for incontinence.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 876.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, regarding general requirements concerning records, and § 820.198, regarding complaint files.

270. Section 876.5970 is amended by revising paragraph (b) to read as follows:

§ 876.5970 Hernia support.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 876.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, regarding general requirements concerning records, and § 820.198, regarding complaint files.

PART 878—GENERAL AND PLASTIC SURGERY DEVICES

271. The authority citation for 21 CFR continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

272. Section 878.1800 is amended by revising paragraph (b) to read as follows:

§ 878.1800 Speculum and accessories.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 878.9.

273. Section 878.3750 is amended by revising paragraph (b) to read as follows:

§ 878.3750 External prosthesis adhesive.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 878.9.

274. Section 878.3800 is amended by revising paragraph (b) to read as follows:

§ 878.3800 External aesthetic restoration prosthesis.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 878.9. If the device is intended for use without an external prosthesis adhesive to fasten it to the body, the device is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

275. Section 878.3900 is amended by revising paragraph (b) to read as follows:

§ 878.3900 Inflatable extremity splint.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 878.9.

276. Section 878.4160 is amended by revising paragraph (b) to read as follows:

§ 878.4160 Surgical camera and accessories.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 878.9.

277. Section 878.4380 is amended by revising paragraph (b) to read as follows:

§ 878.4380 Drape adhesive.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 878.9.

278. Section 878.4440 is amended by revising paragraph (b) to read as follows:

§ 878.4440 Eye pad.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 878.9.

279. Section 878.4450 is amended by revising paragraph (b) to read as follows:

§ 878.4450 Nonabsorbable gauze for internal use.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 878.9.

280. Section 878.4460 is amended by revising paragraph (b) to read as follows:

§ 878.4460 Surgeon's glove.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 878.9.

281. Section 878.4470 is amended by revising paragraph (b) to read as follows:

§ 878.4470 Surgeon's gloving cream.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 878.9.

282. Section 878.4635 is amended by revising paragraph (b) to read as follows:

§ 878.4635 Ultraviolet lamp for tanning.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 878.9.

283. Section 878.4660 is amended by revising paragraph (b) to read as follows:

§ 878.4660 Skin marker.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 878.9.

284. Section 878.4700 is amended by revising paragraph (b) to read as follows:

§ 878.4700 Surgical microscope and accessories.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 878.9.

285. Section 878.4730 is amended by revising paragraph (b) to read as follows:

§ 878.4730 Surgical skin degreaser or adhesive tape solvent.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 878.9.

286. Section 878.4800 is amended by revising paragraph (b) to read as follows:

§ 878.4800 Manual surgical instrument for general use.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 878.9.

287. Section 878.4810 is amended by revising paragraph (b)(2) to read as follows:

§ 878.4810 Laser surgical instrument for use in general and plastic surgery and in dermatology.

* * * * *

(b) * * *
(2) Class I for special laser gas mixtures used as a lasing medium for this class of lasers. The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 878.9.

288. Section 878.4930 is amended by revising paragraph (b) to read as follows:

§ 878.4930 Suture retention device.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 878.9.

289. Section 878.4950 is amended by revising paragraph (b) to read as follows:

§ 878.4950 Manual operating table and accessories and manual operating chair and accessories.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 878.9.

290. Section 878.5350 is amended by revising paragraph (b) to read as follows:

§ 878.5350 Needle-type epilator.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 878.9.

291. Section 878.5900 is amended by revising paragraph (b) to read as follows:

§ 878.5900 Nonpneumatic tourniquet.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 878.9.

292. Section 878.5910 is amended by revising paragraph (b) to read as follows:

§ 878.5910 Pneumatic tourniquet.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 878.9.

PART 880—GENERAL HOSPITAL AND PERSONAL USE DEVICES

293. The authority citation for 21 CFR part 880 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

294. Section 880.2400 is amended by revising paragraph (b) to read as follows:

§ 880.2400 Bed-patient monitor.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 880.9.

295. Section 880.2700 is amended by revising paragraph (b) to read as follows:

§ 880.2700 Stand-on patient scale.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9. The device also is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

296. Section 880.2720 is amended by revising paragraph (b) to read as follows:

§ 880.2720 Patient scale.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in

subpart E of part 807 of this chapter subject to the limitations in § 880.9.

297. Section 880.2740 is amended by revising paragraph (b) to read as follows:

§ 880.2740 Surgical sponge scale.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9. The device also is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

298. Section 880.2900 is amended by revising paragraph (b) to read as follows:

§ 880.2900 Clinical color change thermometer.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9.

299. Section 880.5075 is amended by revising paragraph (b) to read as follows:

§ 880.5075 Elastic bandage.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9. The device also is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

300. Section 880.5110 is amended by revising paragraph (b) to read as follows:

§ 880.5110 Hydraulic adjustable hospital bed.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9.

301. Section 880.5120 is amended by revising paragraph (b) to read as follows:

§ 880.5120 Manual adjustable hospital bed.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9. The device is also exempt from the current good manufacturing practice regulations

in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

302. Section 880.5150 is amended by revising paragraph (b) to read as follows:

§ 880.5150 Nonpowered flotation therapy mattress.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9. The device also is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

303. Section 880.5160 is amended by revising paragraph (b) to read as follows:

§ 880.5160 Therapeutic medical binder.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9. If the device is not labeled or otherwise represented as sterile, it is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

304. Section 880.5180 is amended by revising paragraph (b) to read as follows:

§ 880.5180 Burn sheet.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9.

305. Section 880.5210 is amended by revising paragraph (b) to read as follows:

§ 880.5210 Intravascular catheter securement device.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9.

306. Section 880.5240 is amended by revising paragraph (b) to read as follows:

§ 880.5240 Medical adhesive tape and adhesive bandage.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the

premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9.

307. Section 880.5300 is amended by revising paragraph (b) to read as follows:

§ 880.5300 Medical absorbent fiber.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9. If the device is not labeled or otherwise represented as sterile, it is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

308. Section 880.5510 is amended by revising paragraph (b) to read as follows:

§ 880.5510 Non-AC-powered patient lift.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9.

309. Section 880.5560 is amended by revising paragraph (b) to read as follows:

§ 880.5560 Temperature regulated water mattress.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9.

310. Section 880.5630 is amended by revising paragraph (b) to read as follows:

§ 880.5630 Nipple shield.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9.

311. Section 880.5640 is amended by revising paragraph (b) to read as follows:

§ 880.5640 Lamb feeding nipple.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9. If the device is not labeled or otherwise represented as sterile, it is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

312. Section 880.5680 is amended by revising paragraph (b) to read as follows:

§ 880.5680 Pediatric position holder.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

313. Section 880.5740 is amended by revising paragraph (b) to read as follows:

§ 880.5740 Suction snakebite kit.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9.

314. Section 880.5780 is amended by revising paragraph (b)(2) to read as follows:

§ 880.5780 Medical support stocking.

* * * * *

(b) * * * * *
(2) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

315. Section 880.5820 is amended by revising paragraph (b) to read as follows:

§ 880.5820 Therapeutic scrotal support.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9. The device also is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

316. Section 880.5950 is amended by revising paragraph (b) to read as follows:

§ 880.5950 Umbilical occlusion device.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the

premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9.

317. Section 880.6025 is amended by revising paragraph (b) to read as follows:

§ 880.6025 Absorbent tipped applicator.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9. If the device is not labeled or otherwise represented as sterile, it is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

318. Section 880.6050 is amended by revising paragraph (b) to read as follows:

§ 880.6050 Ice bag.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9. If the device is not labeled or otherwise represented as sterile, it is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

319. Section 880.6060 is amended by revising paragraph (b) to read as follows:

§ 880.6060 Medical disposable bedding.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9. If the device is not labeled or otherwise represented as sterile, it is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

320. Section 880.6070 is amended by revising paragraph (b) to read as follows:

§ 880.6070 Bed board.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9. The device is also exempt from the current good manufacturing practice regulations

in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

321. Section 880.6080 is amended by revising paragraph (b) to read as follows:

§ 880.6080 Cardiopulmonary resuscitation board.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

322. Section 880.6085 is amended by revising paragraph (b) to read as follows:

§ 880.6085 Hot/cold water bottle.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

323. Section 880.6140 is amended by revising paragraph (b) to read as follows:

§ 880.6140 Medical chair and table.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

324. Section 880.6150 is amended by revising paragraph (b) to read as follows:

§ 880.6150 Ultrasonic cleaner for medical instruments.

* * * * *

(b) *Classification.* Class I. The device, including any solutions intended for use with the device for cleaning and sanitizing the instruments, is exempt from the premarket notification procedures in subpart E of part 807 of

this chapter, subject to the limitations in § 880.9.

325. Section 880.6185 is amended by revising paragraph (b) to read as follows:

§ 880.6185 Cast cover.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9. If the device is not labeled or otherwise represented as sterile, it is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

326. Section 880.6190 is amended by revising paragraph (b) to read as follows:

§ 880.6190 Mattress cover for medical purposes.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9. If the device is not labeled or otherwise represented as sterile, it is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

327. Section 880.6200 is amended by revising paragraph (b) to read as follows:

§ 880.6200 Ring cutter.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9. The device also is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

328. Section 880.6230 is amended by revising paragraph (b) to read as follows:

§ 880.6230 Tongue depressor.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9. If the device is not labeled or otherwise represented as sterile, it is also exempt from the current good manufacturing practice regulations in part 820 of this

chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

329. Section 880.6250 is amended by revising paragraph (b) to read as follows:

§ 880.6250 Patient examination glove.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9.

330. Section 880.6265 is amended by revising paragraph (b) to read as follows:

§ 880.6265 Examination gown.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9. If the device is not labeled or otherwise represented as sterile, it is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

331. Section 880.6280 is amended by revising paragraph (b) to read as follows:

§ 880.6280 Medical insole.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9.

332. Section 880.6320 is amended by revising paragraph (b) to read as follows:

§ 880.6320 AC-powered medical examination light.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9.

333. Section 880.6350 is amended by revising paragraph (b) to read as follows:

§ 880.6350 Battery-powered medical examination light.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9. The device also is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning

records, and § 820.198, with respect to complaint files.

334. Section 880.6375 is amended by revising paragraph (b) to read as follows:

§ 880.6375 Patient lubricant.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9.

335. Section 880.6430 is amended by revising paragraph (b) to read as follows:

§ 880.6430 Liquid medication dispenser.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

336. Section 880.6450 is amended by revising paragraph (b) to read as follows:

§ 880.6450 Skin pressure protectors.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

337. Section 880.6730 is revised to read as follows:

§ 880.6730 Body waste receptacle.

(a) *Identification.* A body waste receptacle is a device intended for medical purposes that is not attached to the body and that is used to collect the body wastes of a bed patient.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9. The device also is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

338. Section 880.6760 is amended by revising paragraph (b) to read as follows:

§ 880.6760 Protective restraint.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9.

339. Section 880.6785 is amended by revising paragraph (b) to read as follows:

§ 880.6785 Manual patient transfer device.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

340. Section 880.6800 is amended by revising paragraph (b) to read as follows:

§ 880.6800 Washers for body waste receptacles.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9. The device also is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

341. Section 880.6820 is amended by revising paragraph (b) to read as follows:

§ 880.6820 Medical disposable scissors.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9.

342. Section 880.6900 is amended by revising paragraph (b) to read as follows:

§ 880.6900 Hand-carried stretcher.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

343. Section 880.6960 is amended by revising paragraph (b) to read as follows:

§ 880.6960 Irrigating syringe.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9. If the device is not labeled or otherwise represented as sterile, it is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

344. Section 880.6970 is amended by revising paragraph (b) to read as follows:

§ 880.6970 Liquid crystal vein locator.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9.

345. Section 880.6980 is amended by revising paragraph (b) to read as follows:

§ 880.6980 Vein stabilizer.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9. If the device is not labeled or otherwise represented as sterile, it is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

PART 882—NEUROLOGICAL DIAGNOSTIC DEVICES

346. The authority citation for 21 CFR part 882 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

347. Section 882.1030 is amended by revising paragraph (b) to read as follows:

§ 882.1030 Ataxiagraph.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 882.9.

348. Section 882.1410 is amended by revising paragraph (b) to read as follows:

§ 882.1410 Electroencephalograph electrode/lead tester.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 882.9.

349. Section 882.1420 is amended by revising paragraph (b) to read as follows:

§ 882.1420 Electroencephalogram (EEG) signal spectrum analyzer.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 882.9.

350. Section 882.1430 is amended by revising paragraph (b) to read as follows:

§ 882.1430 Electroencephalograph test signal generator.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 882.9.

351. Section 882.1525 is amended by revising paragraph (b) to read as follows:

§ 882.1525 Tuning fork.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 882.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

352. Section 882.1700 is amended by revising paragraph (b) to read as follows:

§ 882.1700 Percussor.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 882.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

353. Section 882.1925 is amended by revising paragraph (b) to read as follows:

§ 882.1925 Ultrasonic scanner calibration test block.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in

subpart E of part 807 of this chapter subject to the limitations in § 882.9.

354. Section 882.4030 is amended by revising paragraph (b) to read as follows:

§ 882.4030 Skull plate anvil.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 882.9.

355. Section 882.4125 is amended by revising paragraph (b) to read as follows:

§ 882.4125 Neurosurgical chair.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 882.9.

356. Section 882.4200 is amended by revising paragraph (b) to read as follows:

§ 882.4200 Clip removal instrument.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 882.9.

357. Section 882.4215 is amended by revising paragraph (b) to read as follows:

§ 882.4215 Clip rack.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 882.9.

358. Section 882.4325 is amended by revising paragraph (b) to read as follows:

§ 882.4325 Cranial drill handpiece (brace).

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 882.9.

359. Section 882.4440 is amended by revising paragraph (b) to read as follows:

§ 882.4440 Neurosurgical headrests.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 882.9.

360. Section 882.4500 is amended by revising paragraph (b) to read as follows:

§ 882.4500 Cranioplasty material forming instrument.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the

premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 882.9.

361. Section 882.4525 is amended by revising paragraph (b) to read as follows:

§ 882.4525 Microsurgical instrument.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 882.9.

362. Section 882.4535 is amended by revising paragraph (b) to read as follows:

§ 882.4535 Nonpowered neurosurgical instrument.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 882.9.

363. Section 882.4600 is amended by revising paragraph (b) to read as follows:

§ 882.4600 Leukotome.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 882.9.

364. Section 882.4900 is amended by revising paragraph (b) to read as follows:

§ 882.4900 Skullplate screwdriver.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 882.9.

PART 884—OBSTETRICAL AND GYNECOLOGICAL DEVICES

365. The authority citation for 21 CFR part 884 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

366. Section 884.1550 is amended by revising paragraph (b) to read as follows:

§ 884.1550 Amniotic fluid sampler (amniocentesis tray).

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 884.9.

367. Section 884.1640 is amended by revising paragraph (b)(2) to read as follows:

§ 884.1640 Culdoscope and accessories.

* * * * *

(b) * * *

(2) Class I for culdoscope accessories that are not part of a specialized instrument or device delivery system; do not have adapters, connectors, channels, or do not have portals for electrosurgical, laser, or other power sources. Such culdoscope accessory instruments include: lens cleaning brush, biopsy brush, clip applier (without clips), applicator, cannula (without trocar or valves), ligature carrier/needle holder, clamp/hemostat/grasper, curette, instrument guide, ligature passing and knotting instrument, suture needle (without suture), retractor, mechanical (noninflatable), snare, stylet, forceps, dissector, mechanical (noninflatable) scissors, and suction/irrigation probe. The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 884.9.

368. Section 884.1690 is amended by revising paragraph (b)(2) to read as follows:

§ 884.1690 Hysteroscope and accessories.

* * * * *

(b) * * *
(2) Class I for hysteroscope accessories that are not part of a specialized instrument or device delivery system; do not have adapters, connectors, channels, or do not have portals for electrosurgical, laser, or other power sources. Such hysteroscope accessory instruments include: lens cleaning brush, cannula (without trocar or valves), clamp/hemostat/grasper, curette, instrument guide, forceps, dissector, mechanical (noninflatable), and scissors. The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 884.9.

369. Section 884.1700 is amended by revising paragraph (b)(2) to read as follows:

§ 884.1700 Hysteroscopic insufflator.

* * * * *

(b) * * *
(2) Class I for tubing and tubing/filter fits which only include accessory instruments that are not used to effect intrauterine access, e.g., hysteroscopic introducer sheaths, etc.; and single-use tubing kits used for only intrauterine insufflation. The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 884.9.

370. Section 884.1720 is amended by revising paragraph (b)(2) to read as follows:

§ 884.1720 Gynecologic laparoscope and accessories.

* * * * *

(b) * * *

(2) Class I for gynecologic laparoscope accessories that are not part of a specialized instrument or device delivery system, do not have adapters, connector channels, or do not have portals for electrosurgical, lasers, or other power sources. Such gynecologic laparoscope accessory instruments include: the lens cleaning brush, biopsy brush, clip applicator (without clips), applicator, cannula (without trocar or valves), ligature carrier/needle holder, clamp/hemostat/grasper, curette, instrument guide, ligature passing and knotting instrument, suture needle (without suture), retractor, mechanical (noninflatable), snare, stylet, forceps, dissector, mechanical (noninflatable), scissors, and suction/irrigation probe. The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 884.9.

371. Section 884.1730 is amended by revising paragraph (b)(2) to read as follows:

§ 884.1730 Laparoscopic insufflator.

* * * * *

(b) * * *

(2) Class I for tubing and tubing/filter kits which include accessory instruments that are not used to effect intra-abdominal insufflation (pneumoperitoneum). The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 884.9.

372. Section 884.2900 is amended by revising paragraph (b) to read as follows:

§ 884.2900 Fetal stethoscope.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 884.9.

373. Section 884.2980 is amended by revising paragraph (a)(2) to read as follows:

§ 884.2980 Telethermographic system.

(a) * * *

(2) *Classification.* Class I (general controls). The devices subject to this paragraph (a)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 884.9.

* * * * *

374. Section 884.2982 is amended by revising paragraph (a)(2) to read as follows:

§ 884.2982 Liquid crystal thermographic system.

(a) * * *

(2) *Classification.* Class I (general controls). The devices subject to this paragraph (a)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 884.9.

* * * * *

375. Section 884.4520 is amended by revising paragraph (b) to read as follows:

§ 884.4520 Obstetric-gynecologic general manual instrument.

* * * * *

(b) *Classification.* Class I (general controls). The devices are exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 884.9.

376. Section 884.4530 is amended by revising paragraph (b)(2) to read as follows:

§ 884.4530 Obstetric-gynecologic specialized manual instrument.

* * * * *

(b) * * *

(2) Class I for the amniotome, uterine curette, cervical dilator (fixed-size bougies), cerclage needle, IUD remover, uterine sound, and gynecological biopsy forceps. The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 884.9.

377. Section 884.5150 is amended by revising paragraph (b) to read as follows:

§ 884.5150 Nonpowered breast pump.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 884.9, if the device is using either a bulb or telescoping mechanism which does not develop more than 250 mm Hg suction, and the device materials that contact breast or breast milk do not produce cytotoxicity, irritation, or sensitization effects.

378. Section 884.5425 is amended by revising paragraph (b)(1) to read as follows:

§ 884.5425 Scented or scented deodorized menstrual pad.

* * * * *

(b) *Classification.* (1) Class I (general controls) for menstrual pads made of common cellulosic and synthetic material with an established safety profile. The devices subject to this

paragraph (b)(1) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 884.9. This exemption does not include the [intralabial] pads and reusable menstrual pads.

* * * * *

379. Section 884.5900 is amended by revising paragraph (b)(2) to read as follows:

§ 884.5900 Therapeutic vaginal douche apparatus.

* * * * *

(b) * * *

(2) Class I if the device is operated by gravity feed. Devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 884.9.

380. Section 884.5920 is amended by revising paragraph (b) to read as follows:

§ 884.5920 Vaginal insufflator.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 884.9.

381. Section 884.6190 is amended by revising paragraph (b) to read as follows:

§ 884.6190 Assisted reproductive microscopes and microscope accessories.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 884.9.

PART 886—OPHTHALMIC DEVICES

382. The authority citation for 21 CFR part 886 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

383. Section 886.1040 is amended by revising paragraph (b) to read as follows:

§ 886.1040 Ocular esthesiometer.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9.

384. Section 886.1050 is amended by revising paragraph (b) to read as follows:

§ 886.1050 Adaptometer (biophotometer).

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9.

385. Section 886.1070 is amended by revising paragraph (b) to read as follows:

§ 886.1070 Anomaloscope.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9.

386. Section 886.1090 is amended by revising paragraph (b) to read as follows:

§ 886.1090 Haidinger brush.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9.

387. Section 886.1140 is amended by revising paragraph (b) to read as follows:

§ 886.1140 Ophthalmic chair.

* * * * *

(b) *Classification.* Class I. The AC-powered device and the manual device are exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The manual device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

388. Section 886.1150 is amended by revising paragraph (b) to read as follows:

§ 886.1150 Visual acuity chart.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

389. Section 886.1160 is amended by revising paragraph (b) to read as follows:

§ 886.1160 Color vision plate illuminator.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9.

390. Section 886.1170 is amended by revising paragraph (b) to read as follows:

§ 886.1170 Color vision tester.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

391. Section 886.1190 is amended by revising paragraph (b) to read as follows:

§ 886.1190 Distometer.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

392. Section 886.1200 is amended by revising paragraph (b) to read as follows:

§ 886.1200 Optokinetic drum.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

393. Section 886.1250 is amended by revising paragraph (b) to read as follows:

§ 886.1250 Euthyscope.

* * * * *

(b) *Classification.* Class I for the battery powered device. The battery powered device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. Class II for the AC-powered device.

394. Section 886.1270 is amended by revising paragraph (b) to read as follows:

§ 886.1270 Exophthalmometer.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9.

395. Section 886.1290 is amended by revising paragraph (b) to read as follows:

§ 886.1290 Fixation device.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9.

396. Section 886.1320 is amended by revising paragraph (b) to read as follows:

§ 886.1320 Fornixscope.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

397. Section 886.1330 is amended by revising paragraph (b) to read as follows:

§ 886.1330 Amsler grid.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

398. Section 886.1340 is amended by revising paragraph (b) to read as follows:

§ 886.1340 Haploscope.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9.

399. Section 886.1375 is amended by revising paragraph (b) to read as follows:

§ 886.1375 Bagolini lens.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

400. Section 886.1380 is amended by revising paragraph (b) to read as follows:

§ 886.1380 Diagnostic condensing lens.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

401. Section 886.1390 is amended by revising paragraph (b) to read as follows:

§ 886.1390 Flexible diagnostic Fresnel lens.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

402. Section 886.1395 is amended by revising paragraph (b) to read as follows:

§ 886.1395 Diagnostic Hruby fundus lens.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

403. Section 886.1400 is amended by revising paragraph (b) to read as follows:

§ 886.1400 Maddox lens.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

404. Section 886.1405 is amended by revising paragraph (b) to read as follows:

§ 886.1405 Ophthalmic trial lens set.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9.

405. Section 886.1410 is amended by revising paragraph (b) to read as follows:

§ 886.1410 Ophthalmic trial lens clip.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9.

406. Section 886.1415 is amended by revising paragraph (b) to read as follows:

§ 886.1415 Ophthalmic trial lens frame.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

407. Section 886.1420 is amended by revising paragraph (b) to read as follows:

§ 886.1420 Ophthalmic lens gauge.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9.

408. Section 886.1425 is amended by revising paragraph (b) to read as follows:

§ 886.1425 Lens measuring instrument.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9.

409. Section 886.1430 is amended by revising paragraph (b) to read as follows:

§ 886.1430 Ophthalmic contact lens radius measuring device.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9.

410. Section 886.1435 is amended by revising paragraph (b) to read as follows:

§ 886.1435 Maxwell spot.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9.

411. Section 886.1450 is amended by revising paragraph (b) to read as follows:

§ 886.1450 Corneal radius measuring device.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9, only when the device does not include computer software in the unit or topographers.

412. Section 886.1460 is amended by revising paragraph (b) to read as follows:

§ 886.1460 Stereopsis measuring instrument.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

413. Section 886.1500 is amended by revising paragraph (b) to read as follows:

§ 886.1500 Headband mirror.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

414. Section 886.1605 is amended by revising paragraph (b) to read as follows:

§ 886.1605 Perimeter.

* * * * *

(b) *Classification.* Class I (general controls). The manual device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements

concerning records, and § 820.198, with respect to complaint files.

415. Section 886.1650 is amended by revising paragraph (b) to read as follows:

§ 886.1650 Ophthalmic bar prism.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

416. Section 886.1655 is amended by revising paragraph (b) to read as follows:

§ 886.1655 Ophthalmic Fresnel prism.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

417. Section 886.1660 is amended by revising paragraph (b) to read as follows:

§ 886.1660 Gonioscopic prism.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9.

418. Section 886.1665 is amended by revising paragraph (b) to read as follows:

§ 886.1665 Ophthalmic rotary prism.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

419. Section 886.1680 is amended by revising paragraph (b) to read as follows:

§ 886.1680 Ophthalmic projector.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the

premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9.

420. Section 886.1690 is amended by revising paragraph (b) to read as follows:

§ 886.1690 Pupillograph.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9.

421. Section 886.1700 is amended by revising paragraph (b) to read as follows:

§ 886.1700 Pupilometer.

* * * * *

(b) *Classification.* Class I (general controls). The AC-powered device and the manual device are exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The manual device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

422. Section 886.1750 is amended by revising paragraph (b) to read as follows:

§ 886.1750 Skiascopic rack.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9.

423. Section 886.1760 is amended by revising paragraph (b) to read as follows:

§ 886.1760 Ophthalmic refractometer.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9.

424. Section 886.1770 is amended by revising paragraph (b) to read as follows:

§ 886.1770 Manual refractor.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

425. Section 886.1790 is amended by revising paragraph (b) to read as follows:

§ 886.1790 Nearpoint ruler.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

426. Section 886.1800 is amended by revising paragraph (b) to read as follows:

§ 886.1800 Schirmer strip.

* * * * *

(b) *Classification.* Class I (general controls). If the device is made of the same materials that were used in the device before May 28, 1976, the device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9.

427. Section 886.1810 is amended by revising paragraph (b) to read as follows:

§ 886.1810 Tangent screen (campimeter).

* * * * *

(b) *Classification.* Class I (general controls). The AC-powered device and the battery-powered device are exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The battery-powered device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

428. Section 886.1840 is amended by revising paragraph (b) to read as follows:

§ 886.1840 Simultan (including crossed cylinder).

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

429. Section 886.1860 is amended by revising paragraph (b) to read as follows:

§ 886.1860 Ophthalmic instrument stand.

* * * * *

(b) *Classification*. Class I (general controls). The AC-powered device and the battery-powered device are exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The battery-powered device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

430. Section 886.1870 is amended by revising paragraph (b) to read as follows:

§ 886.1870 Stereoscope.

* * * * *

(b) *Classification*. Class I (general controls). The AC-powered device and the battery-powered device are exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The battery-powered device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

431. Section 886.1880 is amended by revising paragraph (b) to read as follows:

§ 886.1880 Fusion and stereoscopic target.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

432. Section 886.1905 is amended by revising paragraph (b) to read as follows:

§ 886.1905 Nystagmus tape.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

433. Section 886.1910 is amended by revising paragraph (b) to read as follows:

§ 886.1910 Spectacle dissociation test system.

* * * * *

(b) *Classification*. Class I (general controls). The AC-powered device and the battery-powered device are exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The battery-powered device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

434. Section 886.1945 is amended by revising paragraph (b) to read as follows:

§ 886.1945 Transilluminator.

* * * * *

(b) *Classification*. Class I for the battery-powered device. The battery-powered device is also exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. Class II for the AC-powered device.

435. Section 886.3200 is amended by revising paragraph (b) to read as follows:

§ 886.3200 Artificial eye.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9, if the device is made from the same materials, has the same chemical composition, and uses the same manufacturing processes as currently legally marketed devices.

436. Section 886.4230 is amended by revising paragraph (b) to read as follows:

§ 886.4230 Ophthalmic knife test drum.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

437. Section 886.4250 is amended by revising paragraph (b) to read as follows:

§ 886.4250 Ophthalmic electrolysis unit.

* * * * *

(b) *Classification*. Class I for the battery-powered device. Class II for the AC-powered device. The battery-

powered device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9.

438. Section 886.4335 is amended by revising paragraph (b) to read as follows:

§ 886.4335 Operating headlamp.

* * * * *

(b) *Classification*. Class I for the battery-powered device. Class II for the AC-powered device. The battery-powered device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9.

439. Section 886.4350 is amended by revising paragraph (b) to read as follows:

§ 886.4350 Manual ophthalmic surgical instrument.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9.

440. Section 886.4360 is amended by revising paragraph (b) to read as follows:

§ 886.4360 Ocular surgery irrigation device.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9.

441. Section 886.4445 is amended by revising paragraph (b) to read as follows:

§ 886.4445 Permanent magnet.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

442. Section 886.4570 is amended by revising paragraph (b) to read as follows:

§ 886.4570 Ophthalmic surgical marker.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9.

443. Section 886.4770 is amended by revising paragraph (b) to read as follows:

§ 886.4770 Ophthalmic operating spectacles (loupes).

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

444. Section 886.4855 is amended by revising paragraph (b) to read as follows:

§ 886.4855 Ophthalmic instrument table.

* * * * *

(b) *Classification*. Class I (general controls). The AC-powered device and the manual device are exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The manual device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

445. Section 886.5120 is amended by revising paragraph (b) to read as follows:

§ 886.5120 Low-power binocular loupe.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

446. Section 886.5420 is amended by revising paragraph (b) to read as follows:

§ 886.5420 Contact lens inserter/remover.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9.

447. Section 886.5540 is amended by revising paragraph (b) to read as follows:

§ 886.5540 Low-vision magnifier.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The device is also exempt from the current good manufacturing practice regulations

in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

448. Section 886.5600 is amended by revising paragraph (b) to read as follows:

§ 886.5600 Ptosic crutch.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

449. Section 886.5800 is amended by revising paragraph (b) to read as follows:

§ 886.5800 Ophthalmic bar reader.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

450. Section 886.5810 is amended by revising paragraph (b) to read as follows:

§ 886.5810 Ophthalmic prism reader.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

451. Section 886.5820 is amended by revising paragraph (b) to read as follows:

§ 886.5820 Closed-circuit television reading system.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9.

452. Section 886.5840 is amended by revising paragraph (b) to read as follows:

§ 886.5840 Magnifying spectacles.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9.

453. Section 886.5842 is amended by revising paragraph (b) to read as follows:

§ 886.5842 Spectacle frame.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9.

454. Section 886.5844 is amended by revising paragraph (b) to read as follows:

§ 886.5844 Prescription spectacle lens.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9.

455. Section 886.5870 is amended by revising paragraph (b) to read as follows:

§ 886.5870 Low-vision telescope.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

456. Section 886.5900 is amended by revising paragraph (b) to read as follows:

§ 886.5900 Electronic vision aid.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9.

457. Section 886.5910 is amended by revising paragraph (b) to read as follows:

§ 886.5910 Image intensification vision aid.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning

records, and § 820.198, with respect to complaint files.

458. Section 886.5915 is amended by revising paragraph (b) to read as follows:

§ 886.5915 Optical vision aid.

* * * * *

(b) *Classification.* Class I (general controls). The AC-powered device and the battery-powered device are exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The battery-powered device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

PART 888—ORTHOPEDIC DEVICES

459. The authority citation for 21 CFR part 888 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

460. Section 888.1100 is amended by revising paragraph (b)(2) to read as follows:

§ 888.1100 Arthroscope.

* * * * *

(b) * * *
(2) Class I for the following manual arthroscopic instruments: cannulas, curettes, drill guides, forceps, gouges, graspers, knives, obturators, osteotomes, probes, punches, rasps, retractors, rongeurs, suture passers, suture knotpushers, suture punches, switching rods, and trocars. The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 888.9.

461. Section 888.1520 is amended by revising paragraph (b) to read as follows:

§ 888.1520 Nonpowered goniometer.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 888.9.

462. Section 888.3000 is amended by revising paragraph (b) to read as follows:

§ 888.3000 Bone cap.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 888.9.

463. Section 888.4150 is amended by revising paragraph (b) to read as follows:

§ 888.4150 Calipers for clinical use.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 888.9.

464. Section 888.4200 is amended by revising paragraph (b) to read as follows:

§ 888.4200 Cement dispenser.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 888.9.

465. Section 888.4210 is amended by revising paragraph (b) to read as follows:

§ 888.4210 Cement mixer for clinical use.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 888.9.

466. Section 888.4220 is amended by revising paragraph (b) to read as follows:

§ 888.4220 Cement monomer vapor evacuator.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 888.9.

467. Section 888.4230 is amended by revising paragraph (b) to read as follows:

§ 888.4230 Cement ventilation tube.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 888.9.

468. Section 888.4300 is amended by revising paragraph (b) to read as follows:

§ 888.4300 Depth gauge for clinical use.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 888.9.

469. Section 888.4540 is amended by revising paragraph (b) to read as follows:

§ 888.4540 Orthopedic manual surgical instrument.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 888.9.

470. Section 888.4600 is amended by revising paragraph (b) to read as follows:

§ 888.4600 Protractor for clinical use.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 888.9.

471. Section 888.4800 is amended by revising paragraph (b) to read as follows:

§ 888.4800 Template for clinical use.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 888.9.

472. Section 888.5850 is amended by revising paragraph (b) to read as follows:

§ 888.5850 Nonpowered orthopedic traction apparatus and accessories.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 888.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, regarding general requirements concerning records, and § 820.198, regarding complaint files.

473. Section 888.5890 is amended by revising paragraph (b) to read as follows:

§ 888.5890 Noninvasive traction component.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 888.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, regarding general requirements concerning records, and § 820.198, regarding complaint files.

474. Section 888.5940 is amended by revising paragraph (b) to read as follows:

§ 888.5940 Cast component.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 888.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, regarding general requirements concerning records, and § 820.198, regarding complaint files.

475. Section 888.5960 is amended by revising paragraph (b) to read as follows:

§ 888.5960 Cast removal instrument.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 888.9.

476. Section 888.5980 is amended by revising paragraph (b) to read as follows:

§ 888.5980 Manual cast application and removal instrument.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 888.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, regarding general requirements concerning records, and § 820.198, regarding complaint files.

PART 890—PHYSICAL MEDICINE DEVICES

477. The authority citation for 21 CFR part 890 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

478. Section 890.1575 is amended by revising paragraph (b) to read as follows:

§ 890.1575 Force-measuring platform.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 890.9.

479. Section 890.1600 is amended by revising paragraph (b) to read as follows:

§ 890.1600 Intermittent pressure measurement system.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 890.9.

480. Section 890.1615 is amended by revising paragraph (b) to read as follows:

§ 890.1615 Miniature pressure transducer.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 890.9.

481. Section 890.3025 is amended by revising paragraph (b) to read as follows:

§ 890.3025 Prosthetic and orthotic accessory.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 890.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, regarding general requirements concerning records and § 820.198, regarding complaint files.

482. Section 890.3075 is amended by revising paragraph (b) to read as follows:

§ 890.3075 Cane.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 890.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, regarding general requirements concerning records and § 820.198, regarding complaint files.

483. Section 890.3100 is amended by revising paragraph (b) to read as follows:

§ 890.3100 Mechanical chair.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 890.9.

484. Section 890.3150 is amended by revising paragraph (b) to read as follows:

§ 890.3150 Crutch.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 890.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, regarding general requirements concerning records and § 820.198, regarding complaint files.

485. Section 890.3175 is amended by revising paragraph (b) to read as follows:

§ 890.3175 Flotation cushion.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 890.9.

486. Section 890.3410 is amended by revising paragraph (b) to read as follows:

§ 890.3410 External limb orthotic component.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 890.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, regarding general requirements concerning records and § 820.198, regarding complaint files.

487. Section 890.3420 is amended by revising paragraph (b) to read as follows:

§ 890.3420 External limb prosthetic component.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 890.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, regarding general requirements concerning records and § 820.198, regarding complaint files.

488. Section 890.3475 is amended by revising paragraph (b) to read as follows:

§ 890.3475 Limb orthosis.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 890.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, regarding general requirements concerning records and § 820.198, regarding complaint files.

489. Section 890.3490 is amended by revising paragraph (b) to read as follows:

§ 890.3490 Truncal orthosis.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 890.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, regarding general requirements concerning records and § 820.198, regarding complaint files.

490. Section 890.3520 is amended by revising paragraph (b) to read as follows:

§ 890.3520 Plinth.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 890.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, regarding general requirements concerning records and § 820.198, regarding complaint files.

491. Section 890.3640 is amended by revising paragraph (b) to read as follows:

§ 890.3640 Arm sling.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 890.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, regarding general requirements concerning records and § 820.198, regarding complaint files.

492. Section 890.3665 is amended by revising paragraph (b) to read as follows:

§ 890.3665 Congenital hip dislocation abduction splint.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 890.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, regarding general requirements concerning records and § 820.198, regarding complaint files.

493. Section 890.3675 is amended by revising paragraph (b) to read as follows:

§ 890.3675 Denis Brown splint.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 890.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, regarding general requirements concerning records and § 820.198, regarding complaint files.

494. Section 890.3700 is amended by revising paragraph (b) to read as follows:

§ 890.3700 Nonpowered communication system.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 890.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, regarding general requirements concerning records and § 820.198, regarding complaint files.

495. Section 890.3750 is amended by revising paragraph (b) to read as follows:

§ 890.3750 Mechanical table.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 890.9.

496. Section 890.3760 is amended by revising paragraph (b) to read as follows:

§ 890.3760 Powered table.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 890.9.

497. Section 890.3790 is amended by revising paragraph (b) to read as follows:

§ 890.3790 Cane, crutch, and walker tips and pads.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 890.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, regarding general requirements concerning records and § 820.198, regarding complaint files.

498. Section 890.3825 is amended by revising paragraph (b) to read as follows:

§ 890.3825 Mechanical walker.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 890.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, regarding

general requirements concerning records and § 820.198, regarding complaint files.

499. Section 890.3910 is amended by revising paragraph (b) to read as follows:

§ 890.3910 Wheelchair accessory.

* * * * *

(b) *Classification.* Class I (general controls). If the device is not intended for use as a protective restraint as defined in § 880.6760 of this chapter, it is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 890.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, regarding general requirements concerning records, and § 820.198, regarding complaint files.

500. Section 890.3920 is amended by revising paragraph (b) to read as follows:

§ 890.3920 Wheelchair component.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 890.9.

501. Section 890.3940 is amended by revising paragraph (b) to read as follows:

§ 890.3940 Wheelchair platform scale.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 890.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, regarding general requirements concerning records and § 820.198, regarding complaint files.

502. Section 890.5050 is amended by revising paragraph (b) to read as follows:

§ 890.5050 Daily activity assist device.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 890.9. If the device is not labeled or otherwise represented as sterile, the device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, regarding general requirements concerning records and § 820.198, regarding complaint files.

503. Section 890.5125 is amended by revising paragraph (b) to read as follows:

§ 890.5125 Nonpowered sitz bath.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 890.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, regarding general requirements concerning records and § 820.198, regarding complaint files.

504. Section 890.5350 is amended by revising paragraph (b) to read as follows:

§ 890.5350 Exercise component.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 890.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, regarding general requirements concerning records and § 820.198, regarding complaint files.

505. Section 890.5370 is amended by revising paragraph (b) to read as follows:

§ 890.5370 Nonmeasuring exercising equipment.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 890.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, regarding general requirements concerning records and § 820.198, regarding complaint files.

506. Section 890.5380 is amended by revising paragraph (b) to read as follows:

§ 890.5380 Powered exercise equipment.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 890.9.

507. Section 890.5410 is amended by revising paragraph (b) to read as follows:

§ 890.5410 Powered finger exerciser.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in

subpart E of part 807 of this chapter, subject to the limitations in § 890.9.

508. Section 890.5660 is amended by revising paragraph (b) to read as follows:

§ 890.5660 Therapeutic massager.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 890.9.

509. Section 890.5730 is amended by revising paragraph (b) to read as follows:

§ 890.5730 Moist heat pack.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 890.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, regarding general requirements concerning records and § 820.198, regarding complaint files.

510. Section 890.5765 is amended by revising paragraph (b) to read as follows:

§ 890.5765 Pressure-applying device.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 890.9.

511. Section 890.5925 is amended by revising paragraph (b) to read as follows:

§ 890.5925 Traction accessory.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 890.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, regarding general requirements concerning records and § 820.198, regarding complaint files.

512. Section 890.5940 is amended by revising paragraph (b) to read as follows:

§ 890.5940 Chilling unit.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 890.9.

513. Section 890.5950 is amended by revising paragraph (b) to read as follows:

§ 890.5950 Powered heating unit.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 890.9.

514. Section 890.5975 is amended by revising paragraph (b) to read as follows:

§ 890.5975 Therapeutic vibrator.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 890.9.

PART 892—RADIOLOGY DEVICES

515. The authority citation for 21 CFR part 892 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

516. Section 892.1100 is amended by revising paragraph (b) to read as follows:

§ 892.1100 Scintillation (gamma) camera.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 892.9.

517. Section 892.1110 is amended by revising paragraph (b) to read as follows:

§ 892.1110 Positron camera.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 892.9.

518. Section 892.1130 is amended by revising paragraph (b) to read as follows:

§ 892.1130 Nuclear whole body counter.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 892.9.

519. Section 892.1300 is amended by revising paragraph (b) to read as follows:

§ 892.1300 Nuclear rectilinear scanner.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 892.9.

520. Section 892.1370 is amended by revising paragraph (b) to read as follows:

§ 892.1370 Nuclear anthropomorphic phantom.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 892.9.

521. Section 892.1380 is amended by revising paragraph (b) to read as follows:

§ 892.1380 Nuclear flood source phantom.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 892.9.

522. Section 892.1400 is amended by revising paragraph (b) to read as follows:

§ 892.1400 Nuclear sealed calibration source.

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(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 892.9.

523. Section 892.1420 is amended by revising paragraph (b) to read as follows:

§ 892.1420 Radionuclide test pattern phantom.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 892.9.

524. Section 892.1640 is amended by revising paragraph (b) to read as follows:

§ 892.1640 Radiographic film marking system.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 892.9.

525. Section 892.1700 is amended by revising paragraph (b) to read as follows:

§ 892.1700 Diagnostic x-ray high voltage generator.

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(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 892.9.

526. Section 892.1760 is amended by revising paragraph (b) to read as follows:

§ 892.1760 Diagnostic x-ray tube housing assembly.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 892.9.

527. Section 892.1770 is amended by revising paragraph (b) to read as follows:

§ 892.1770 Diagnostic x-ray tube mount.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 892.9.

528. Section 892.1830 is amended by revising paragraph (b) to read as follows:

§ 892.1830 Radiologic patient cradle.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 892.9.

529. Section 892.1840 is amended by revising paragraph (b) to read as follows:

§ 892.1840 Radiographic film.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 892.9.

530. Section 892.1880 is amended by revising paragraph (b) to read as follows:

§ 892.1880 Wall-mounted radiographic cassette holder.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 892.9.

531. Section 892.1920 is amended by revising paragraph (b) to read as follows:

§ 892.1920 Radiographic head holder.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 892.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

532. Section 892.1940 is amended by revising paragraph (b) to read as follows:

§ 892.1940 Radiologic quality assurance instrument.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 892.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

533. Section 892.1950 is amended by revising paragraph (b) to read as follows:

§ 892.1950 Radiographic anthropomorphic phantom.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 892.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

534. Section 892.5740 is amended by revising paragraph (b) to read as follows:

§ 892.5740 Radionuclide teletherapy source.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 892.9.

535. Section 892.5780 is amended by revising paragraph (b) to read as follows:

§ 892.5780 Light beam patient position indicator.

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(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 892.9.

Dated: June 21, 2001.

Linda S. Kahan,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

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