

- 880.5725 Infusion pump.
- 880.5740 Suction snakebite kit.
- 880.5760 Chemical cold pack snakebite kit.
- 880.5780 Medical support stocking.
- 880.5820 Therapeutic scrotal support.
- 880.5860 Piston syringe.
- 880.5950 Umbilical occlusion device.

Subpart G—General Hospital and Personal Use Miscellaneous Devices

- 880.6025 Absorbent tipped applicator.
- 880.6050 Ice bag.
- 880.6060 Medical disposable bedding.
- 880.6070 Bed board.
- 880.6080 Cardiopulmonary resuscitation board.
- 880.6085 Hot/cold water bottle.
- 880.6100 Ethylene oxide gas aerator cabinet.
- 880.6140 Medical chair and table.
- 880.6150 Ultrasonic cleaner for medical instruments.
- 880.6175 [Reserved]
- 880.6185 Cast cover.
- 880.6190 Mattress cover for medical purposes.
- 880.6200 Ring cutter.
- 880.6230 Tongue depressor.
- 880.6250 Patient examination glove.
- 880.6265 Examination gown.
- 880.6280 Medical insole.
- 880.6320 AC-powered medical examination light.
- 880.6350 Battery-powered medical examination light.
- 880.6375 Patient lubricant.
- 880.6430 Liquid medication dispenser.
- 880.6450 Skin pressure protectors.
- 880.6500 Medical ultraviolet air purifier.
- 880.6710 Medical ultraviolet water purifier.
- 880.6730 Body waste receptacle.
- 880.6740 Vacuum-powered body fluid suction apparatus.
- 880.6760 Protective restraint.
- 880.6775 Powered patient transfer device.
- 880.6785 Manual patient transfer device.
- 880.6800 Washer for body waste receptacles.
- 880.6820 Medical disposable scissors.
- 880.6850 Sterilization wrap.
- 880.6860 Ethylene oxide gas sterilizer.
- 880.6870 Dry-heat sterilizer.
- 880.6880 Steam sterilizer.
- 880.6900 Hand-carried stretcher.
- 880.6910 Wheeled stretcher.
- 880.6920 Syringe needle introducer.
- 880.6960 Irrigating syringe.
- 880.6970 Liquid crystal vein locator.
- 880.6980 Vein stabilizer.

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

SOURCE: 45 FR 69682–69737, Oct. 21, 1980, unless otherwise noted.

Subpart A—General Provisions

§ 880.1 Scope.

(a) This part sets forth the classification of general hospital and personal use devices intended for human use that are in commercial distribution.

(b) The identification of a device in a regulation in this part is not a precise description of every device that is, or will be, subject to the regulation. A manufacturer who submits a pre-market notification submission for a device under part 807 may not show merely that the device is accurately described by the section title and identification provisions of a regulation in this part, but shall state why the device is substantially equivalent to other devices, as required by § 807.87.

(c) To avoid duplicative listings, a general hospital and personal use device that has two or more types of uses (e.g., used both as a diagnostic device and as a therapeutic device) is listed only in one subpart.

(d) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21, unless otherwise noted.

[52 FR 17738, May 11, 1987]

§ 880.3 Effective dates of requirement for premarket approval.

A device included in this part that is classified into class III (premarket approval) shall not be commercially distributed after the date shown in the regulation classifying the device unless the manufacturer has an approval under section 515 of the act (unless an exemption has been granted under section 520(g)(2) of the act). An approval under section 515 of the act consists of FDA's issuance of an order approving an application for premarket approval (PMA) for the device or declaring completed a product development protocol (PDP) for the device.

(a) Before FDA requires that a device commercially distributed before the enactment date of the amendments, or a device that has been found substantially equivalent to such a device, has an approval under section 515 of the act FDA must promulgate a regulation under section 515(b) of the act requiring such approval, except as provided

in paragraph (b) of this section. Such a regulation under section 515(b) of the act shall not be effective during the grace period ending on the 90th day after its promulgation or on the last day of the 30th full calendar month after the regulation that classifies the device into class III is effective, whichever is later. See section 501(f)(2)(B) of the act. Accordingly, unless an effective date of the requirement for premarket approval is shown in the regulation for a device classified into class III in this part, the device may be commercially distributed without FDA's issuance of an order approving a PMA or declaring completed a PDP for the device. If FDA promulgates a regulation under section 515(b) of the act requiring premarket approval for a device, section 501(f)(1)(A) of the act applies to the device.

(b) Any new, not substantially equivalent, device introduced into commercial distribution on or after May 28, 1976, including a device formerly marketed that has been substantially altered, is classified by statute (section 513(f) of the act) into class III without any grace period and FDA must have issued an order approving a PMA or declaring completed a PDP for the device before the device is commercially distributed unless it is reclassified. If FDA knows that a device being commercially distributed may be a "new" device defined in this section because of any new intended use or other reasons, FDA may codify the statutory classification of the device into class III for such new use. Accordingly, the regulation for such a class III device states that as of the enactment date of the amendments, May 28, 1976, the device must have an approval under section 515 of the act before commercial distribution.

[52 FR 17738, May 11, 1987]

§ 880.9 Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).

The Food and Drug Administration's (FDA's) decision to grant an exemption from the requirement of premarket notification (section 510(k) of the act) for a generic type of class I device is based upon the existing and reasonably foreseeable characteristics of commer-

cially distributed devices within that generic type. Because FDA cannot anticipate every change in intended use or characteristic that could significantly affect a device's safety or effectiveness, manufacturers of any commercially distributed class I device for which FDA has granted an exemption from the requirement of premarket notification must still submit a premarket notification to FDA before introducing or delivering for introduction into interstate commerce for commercial distribution the device when:

(a) The device is intended for a use different from its intended use before May 28, 1976, or the device is intended for a use different from the intended use of a preamendments device to which it had been determined to be substantially equivalent; e.g., the device is intended for a different medical purpose, or the device is intended for lay use where the former intended use was by health care professionals only; or

(b) The modified device operates using a different fundamental scientific technology than that in use in the device before May 28, 1976; e.g., a surgical instrument cuts tissue with a laser beam rather than with a sharpened metal blade, or an in vitro diagnostic device detects or identifies infectious agents by using a deoxyribonucleic acid (DNA) probe or nucleic acid hybridization technology rather than culture or immunoassay technology.

[54 FR 25050, June 12, 1989]

Subpart B [Reserved]

Subpart C—General Hospital and Personal Use Monitoring Devices

§ 880.2200 Liquid crystal forehead temperature strip.

(a) *Identification.* A liquid crystal forehead temperature strip is a device applied to the forehead that is used to indicate the presence or absence of fever, or to monitor body temperature changes. The device displays the color changes of heat sensitive liquid crystals corresponding to the variation in the surface temperature of the skin.