

§ 878.1

21 CFR Ch. I (4–1–98 Edition)

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

Subpart B—Diagnostic Devices

878.1800 Speculum and accessories.

Subpart C [Reserved]

Subpart D—Prosthetic Devices

878.3250 External facial fracture fixation appliance.
878.3300 Surgical mesh.
878.3500 Polytetrafluoroethylene with carbon fibers composite implant material.
878.3530 Silicone inflatable breast prosthesis.
878.3540 Silicone gel-filled breast prosthesis.
878.3550 Chin prosthesis.
878.3590 Ear prosthesis.
878.3610 Esophageal prosthesis.
878.3680 Nose prosthesis.
878.3720 Tracheal prosthesis.
878.3750 External prosthesis adhesive.
878.3800 External aesthetic restoration prosthesis.
878.3900 Inflatable extremity splint.
878.3910 Noninflatable extremity splint.
878.3925 Plastic surgery kit and accessories.

Subpart E—Surgical Devices

878.4040 Surgical apparel.
878.4100 Organ bag.
878.4160 Surgical camera and accessories.
878.4200 Introduction/drainage catheter and accessories.
878.4300 Implantable clip.
878.4320 Removable skin clip.
878.4350 Cryosurgical unit and accessories.
878.4370 Surgical drape and drape accessories.
878.4380 Drape adhesive.
878.4400 Electrosurgical cutting and coagulation device and accessories.
878.4440 Eye pad.
878.4450 Nonabsorbable gauze for internal use.
878.4460 Surgeon's glove.
878.4470 Surgeon's gloving cream.
878.4480 Absorbable powder for lubricating a surgeon's glove.
878.4490 Absorbable hemostatic agent and dressing.
878.4493 Absorbable poly(glycolide/L-lactide) surgical suture.
878.4520 Polytetrafluoroethylene injectable.
878.4580 Surgical lamp.
878.4630 Ultraviolet lamp for dermatologic disorders.
878.4635 Ultraviolet lamp for tanning.
878.4660 Skin marker.
878.4680 Nonpowered, single patient, portable suction apparatus.
878.4700 Surgical microscope and accessories.

878.4730 Surgical skin degreaser or adhesive tape solvent.
878.4750 Implantable staple.
878.4760 Removable skin staple.
878.4780 Powered suction pump.
878.4800 Manual surgical instrument for general use.
878.4810 Laser surgical instrument for use in general and plastic surgery and in dermatology.
878.4820 Surgical instrument motors and accessories/attachments.
878.4830 Absorbable surgical gut suture.
878.4930 Suture retention device.
878.4950 Manual operating table and accessories and manual operating chair and accessories.
878.4960 Operating tables and accessories and operating chairs and accessories.
878.5000 Nonabsorbable poly(ethylene terephthalate) surgical suture.
878.5010 Nonabsorbable polypropylene surgical suture.
878.5020 Nonabsorbable polyamide surgical suture.
878.5030 Natural nonabsorbable silk surgical suture.
878.5040 Suction lipoplasty system.

Subpart F—Therapeutic Devices

878.5070 Air-handling apparatus for a surgical operating room.
878.5350 Needle-type epilator.
878.5360 Tweezer-type epilator.
878.5650 Topical oxygen chamber for extremities.
878.5900 Nonpneumatic tourniquet.
878.5910 Pneumatic tourniquet.

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

SOURCE: 53 FR 23872, June 24, 1988, unless otherwise noted.

Subpart A—General Provisions

§ 878.1 Scope.

(a) This part sets forth the classification of general and plastic surgery 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 cannot show merely that the device is accurately described by the section title and identification provision of a regulation in this part, but shall state why the device is substantially equivalent to

other devices, as required by § 807.87 of this chapter.

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

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

§ 878.3 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 paragraphs (b) and (c) 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 ap-

proval 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 as 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.

(c) A device identified in a regulation in this part that is classified into class III and that is subject to the transitional provisions of section 520(l) of the act is automatically classified by statute into class III and must have an approval under section 515 of the act before being commercially distributed. Accordingly, the regulation for such a class III transitional 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.

§ 878.9 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 commercially 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