§ 878.1

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.
878.4840 Absorbable polydioxanone surgical 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.
878.5035 Nonabsorbable expanded polytetrafluoroethylene surgical suture.
878.5040 Suction lipectomy 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.
878.5400 Low level laser system for aesthetic use.
878.5650 Topical oxygen chamber for extremities.
878.5900 Nonpneumatic tourniquet.
878.5910 Pneumatic tourniquet.


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

The exemption from the requirement of premarket notification (section 510(k) of the act) for a generic type of class I or II device is only to the extent that the device has existing or reasonably foreseeable characteristics of commercially distributed devices within that generic type or, in the case of in vitro diagnostic devices, only to the extent that misdiagnosis as a result of using the device would not be associated with high morbidity or mortality. Accordingly, manufacturers of any commercially distributed class I or II 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 the intended use of a legally marketed device in that generic type of device; 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;

(b) The modified device operates using a different fundamental scientific technology than a legally marketed device in that generic type of device; 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 deoxyribonucleic acid (DNA) probe or nucleic acid hybridization technology rather than culture or immunoassay technology; or

(c) The device is an in vitro device that is intended:

1. For use in the diagnosis, monitoring, or screening of neoplastic diseases with the exception of immunohistochemical devices;

2. For use in screening or diagnosis of familial or acquired genetic disorders, including inborn errors of metabolism;

3. For measuring an analyte that serves as a surrogate marker for screening, diagnosis, or monitoring...
§ 878.1800 Speculum and accessories.

(a) Identification. A speculum is a device intended to be inserted into a body cavity to aid observation. It is either nonilluminated or illuminated and may have various 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 §878.9.

[65 FR 2317, Jan. 14, 2000]

Subpart C [Reserved]

Subpart D—Prosthetic Devices

§ 878.3250 External facial fracture fixation appliance.

(a) Identification. An external facial fracture fixation appliance is a metal apparatus intended to be used during surgical reconstruction and repair to immobilize maxillofacial bone fragments in their proper facial relationship.

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


§ 878.3300 Surgical mesh.

(a) Identification. Surgical mesh is a metallic or polymeric screen intended to be implanted to reinforce soft tissue or bone where weakness exists. Examples of surgical mesh are metallic and polymeric mesh for hernia repair, and acetalubar and cement restrictor mesh used during orthopedic surgery.

(b) Classification. Class III.

§ 878.3500 Polytetrafluoroethylene with carbon fibers composite implant material.

(a) Identification. A polytetrafluoroethylene with carbon fibers composite implant material is a porous device material intended to be implanted during surgery of the chin, jaw, nose, or bones or tissue near the eye or ear. The device material serves as a space-occupying substance and is shaped and formed by the surgeon to conform to the patient’s need.

(b) Classification. Class III.

§ 878.3530 Silicone inflatable breast prosthesis.

(a) Identification. A silicone inflatable breast prosthesis is a silicone rubber shell made of polysiloxane(s), such as polydimethylsiloxane and polydiphenylsiloxane, that is inflated to the desired size with sterile isotonic saline before or after implantation. The device is intended to be implanted to augment or reconstruct the female breast.

(b) Classification. Class III.

(c) Date PMA or notice of completion of a PDP is required. A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before November 17, 1999, for any silicone inflatable breast prosthesis that was in commercial distribution before May 28, 1976, or that has, on or before November 17, 1999, been found to be substantially equivalent to a silicone inflatable breast prosthesis that was in commercial distribution before