Food and Drug Administration, HHS

PART 878—GENERAL AND PLASTIC SURGERY DEVICES

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

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878.4580 Surgical lamp.
878.4630 Ultraviolet lamp for dermatologic disorders.
878.4635 Ultraviolet lamp for tanning.
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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.
§ 878.3 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.

(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)(1) 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 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 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 has 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 13827, Apr. 5, 1989; 54 FR 16438±T, Apr. 24, 1989]

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. 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.

[53 FR 23872, June 24, 1988, as amended at 54 FR 13827, Apr. 5, 1989]

§ 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 acetabular and cement restrictor mesh used during orthopedic surgery.

(b) Classification. Class II.

§ 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 II.

§ 878.3530 Silicone inflatable breast prosthesis.

(a) Identification. A silicone inflatable breast prosthesis is a silicone rubber shell made of polysiloxanes(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
§ 878.3540 Silicone gel-filled breast prosthesis.
(a) Identification—(1) Single-lumen silicone gel-filled breast prosthesis. A single-lumen silicone gel-filled breast prosthesis is a silicone rubber shell made of polysiloxane(s), such as polydimethylsiloxane and polydiphenylsiloxane. The shell either contains a fixed amount cross-linked polymerized silicone gel, filler, and stabilizers or is filled to the desired size with injectable silicone gel at time of implantation. The device is intended to be implanted to augment or reconstruct the female breast.

(2) Double-lumen silicone gel-filled breast prosthesis. A double lumen silicone gel-filled breast prosthesis is a silicone rubber inner shell and a silicone rubber outer shell, both shells made of polysiloxane(s), such as polydimethylsiloxane and polydiphenylsiloxane. The inner shell contains fixed amounts of cross-linked polymerized silicone gel, fillers, and stabilizers. The outer shell 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.

(3) Polyurethane covered silicone gel-filled breast prosthesis. A polyurethane covered silicone gel-filled breast prosthesis is an inner silicone rubber shell made of polysiloxane(s), such as polydimethylsiloxane and polydiphenylsiloxane, with an outer silicone adhesive layer and an outer covering of polyurethane; contained within the inner shell is a fixed amount of cross-linked polymerized silicone gel, fillers, and stabilizers and an inert support structure compartmentalizing the silicone gel. 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. No effective date has been established of the requirement for premarket approval. See §878.3.

§ 878.3550 Chin prosthesis.
(a) Identification. A chin prosthesis is a silicone rubber solid device intended to be implanted to augment or reconstruct the chin.

(b) Classification. Class II.

§ 878.3590 Ear prosthesis.
(a) Identification. An ear prosthesis is a silicone rubber solid device intended to be implanted to reconstruct the external ear.

(b) Classification. Class II.

§ 878.3610 Esophageal prosthesis.
(a) Identification. An esophageal prosthesis is a plastic tube or tube-like device that may have mesh reinforcement that is intended to be implanted in, or affixed externally to, the chest and throat to restore the esophagus or provide pharyngoesophageal continuity.

(b) Classification. Class III.

(c) Date PMA or notice of completion of a PDP is required. No effective date has been established of the requirement for premarket approval. See §878.3.

§ 878.3680 Nose prosthesis.
(a) Identification. A nose prosthesis is a silicone rubber solid device intended to be implanted to augment or reconstruct the nasal dorsum.

(b) Classification. Class II.

§ 878.3720 Tracheal prosthesis.
(a) Identification. A tracheal prosthesis is a tubular device intended to be implanted to reconstruct the trachea.

(b) Classification. Class III.

(c) Date PMA or notice of completion of a PDP is required. No effective date has
§ 878.3750 External prosthesis adhesive.

(a) Identification. An external prosthesis adhesive is a silicone-type adhesive intended to be used to fasten to the body an external aesthetic restoration prosthesis, such as an artificial nose.

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

§ 878.3800 External aesthetic restoration prosthesis.

(a) Identification. An external aesthetic restoration prosthesis is a device intended to be used to construct an external artificial body structure, such as an ear, breast, or nose. Usually the device is made of silicone rubber and it may be fastened to the body with an external prosthesis adhesive. The device is not intended to be implanted.

(b) Classification. Class I. 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 the general requirements concerning records, and §820.198, with respect to complaint files.

§ 878.3900 Inflatable extremity splint.

(a) Identification. An inflatable extremity splint is a device intended to be inflated to immobilize a limb or an extremity.

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

§ 878.3910 Noninflatable extremity splint.

(a) Identification. A noninflatable extremity splint is a device intended to immobilize a limb or an extremity. It is not inflatable.

(b) Classification. Class I. 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. 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 the general requirements concerning records, and §820.198, with respect to complaint files.

§ 878.3925 Plastic surgery kit and accessories.

(a) Identification. A plastic surgery kit and accessories is a device intended to be used to reconstruct maxillofacial deficiencies. The kit contains surgical instruments and materials used to make maxillofacial impressions before molding an external prosthesis.

(b) Classification. Class I. 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.

§ 878.4040 Surgical apparel.

(a) Identification. Surgical apparel are devices that are intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material. Examples include surgical caps, hoods, masks, gowns, operating room shoes and shoe covers, and isolation masks and gowns. Surgical suits and dresses, commonly known as scrub suits, are excluded.
§ 878.4100 Organ bag.
(a) Identification. An organ bag is a device that is a flexible plastic bag intended to be used as a temporary receptacle for an organ during surgical procedures to prevent moisture loss.
(b) Classification. Class I. The intestinal organ bag device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

§ 878.4160 Surgical camera and accessories.
(a) Identification. A surgical camera and accessories is a device intended to be used to record operative procedures.
(b) Classification. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

§ 878.4200 Introduction/drainage catheter and accessories.
(a) Identification. An introduction/drainage catheter is a device that is a flexible single or multilumen tube intended to be used to introduce nondrug fluids into body cavities other than blood vessels, drain fluids from body cavities, or evaluate certain physiologic conditions. Examples include irrigation and drainage catheters, pediatric catheters, peritoneal catheters (including dialysis), and other general surgical catheters. An introduction/drainage catheter accessory is intended to aid in the manipulation of or insertion of the device into the body. Examples of accessories include adaptors, connectors, and catheter needles.
(b) Classification. Class I.

§ 878.4300 Implantable clip.
(a) Identification. An implantable clip is a clip-like device intended to connect internal tissues to aid healing. It is not absorbable.
(b) Classification. Class II.

§ 878.4320 Removable skin clip.
(a) Identification. A removable skin clip is a clip-like device intended to connect skin tissues temporarily to aid healing. It is not absorbable.
(b) Classification. Class I.

§ 878.4350 Cryosurgical unit and accessories.
(a) Identification—(1) Cryosurgical unit with a liquid nitrogen cooled cryoprobe and accessories. A cryosurgical unit with a liquid nitrogen cooled cryoprobe and accessories is a device intended to destroy tissue during surgical procedures by applying extreme cold.
(2) Cryosurgical unit with a nitrous oxide cooled cryoprobe and accessories. A cryosurgical unit with a nitrous oxide cooled cryoprobe and accessories is a device intended to destroy tissue during surgical procedures, including urological applications, by applying extreme cold.
(3) Cryosurgical unit with a carbon dioxide cooled cryoprobe or a carbon dioxide dry ice applicator and accessories. A cryosurgical unit with a carbon dioxide cooled cryoprobe or a carbon dioxide dry ice applicator and accessories is a device intended to destroy tissue during surgical procedures by applying extreme cold. The device is intended to treat disease conditions such as tumors, skin cancers, acne scars, or hemangiomas (benign tumors consisting of newly formed blood vessels) and various benign or malignant gynecological conditions affecting vulvar, vaginal, or cervical tissue. The device is not intended for urological applications.
(b) Classification. Class II.

§ 878.4370 Surgical drape and drape accessories.
(a) Identification. A surgical drape and drape accessories is a device made of natural or synthetic materials intended to be used as a protective patient covering, such as to isolate a site of surgical incision from microbial and other contamination. The device includes a plastic wound protector that may adhere to the skin around a surgical incision or be placed in a wound to cover its exposed edges, and a latex drape with a self-retaining finger cot.
that is intended to allow repeated inser-
tion of the surgeon’s finger into the
rectum during performance of a
transurethral prostatectomy.
(b) Classification. Class II.

§ 878.4490 Absorbable hemostatic
agent and dressing.
(a) Identification. An absorbable he-
ostatic agent or dressing is a device
intended to produce hemostasis by ac-
celerating the clotting process of
blood. It is absorbable.
(b) Classification. Class III.
(c) Date PMA or notice of completion
of a PDP is required. As of May 28,
1976, an approval under section 515 of
the act is required before this device
may be commercially distributed. See §878.3.

§ 878.4490 Absorbable hemostatic
agent and dressing.

§ 878.3520 Polytetrafluoroethylene injectable.
(a) Identification. Polytetrafluoroethylene injectable is an injectable paste prosthetic device composed of polytetrafluoroethylene intended to be used to augment or reconstruct a vocal cord.
(b) Classification. Class III.
(c) Date PM A or notice of completion of a PDP is required. As of May 28, 1976, an approval under section 515 of the act is required before this device may be commercially distributed. See §878.3.

§ 878.4580 Surgical lamp.
(a) Identification. A surgical lamp (including a fixture) is a device intended to be used to provide visible illumination of the surgical field or the patient.
(b) Classification. Class II.

§ 878.4630 Ultraviolet lamp for dermatologic disorders.
(a) Identification. An ultraviolet lamp for dermatologic disorders is a device (including a fixture) intended to provide ultraviolet radiation of the body to photoactivate a drug in the treatment of a dermatologic disorder if the labeling of the drug intended for use with the device bears adequate directions for the device’s use with that drug.
(b) Classification. Class II.

§ 878.4635 Ultraviolet lamp for tanning.
(a) Identification. An ultraviolet lamp for tanning is a device that is a lamp (including a fixture) intended to provide ultraviolet radiation to tan the skin. See §1040.20 of this chapter.
(b) Classification. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

§ 878.4660 Skin marker.
(a) Identification. A skin marker is a pen-like device intended to be used to write on the patient’s skin, e.g., to outline surgical incision sites or mark anatomical sites for accurate blood pressure measurement.
(b) Classification. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

§ 878.4680 Nonpowered, single patient, portable suction apparatus.
(a) Identification. A nonpowered, single patient, portable suction apparatus is a device that consists of a manually operated plastic, disposable evacuation system intended to provide a vacuum for suction drainage of surgical wounds.
(b) Classification. Class I.

§ 878.4700 Surgical microscope and accessories.
(a) Identification. A surgical microscope and accessories is an AC-powered device intended for use during surgery to provide a magnified view of the surgical field.
(b) Classification. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

§ 878.4730 Surgical skin degreaser or adhesive tape solvent.

(a) Identification. A surgical skin degreaser or an adhesive tape solvent is a device that consists of a liquid such as 1,1,2-trichloro-1,2,2-trifluoroethane; 1,1,1-trichloroethane; and 1,1,1-trichloroethane with mineral spirits intended to be used to dissolve surface skin oil or adhesive tape.

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


§ 878.4750 Implantable staple.

(a) Identification. An implantable staple is a staple-like device intended to connect internal tissues to aid healing. It is not absorbable.

(b) Classification. Class I.

§ 878.4760 Removable skin staple.

(a) Identification. A removable skin staple is a staple-like device intended to connect external tissues temporarily to aid healing. It is not absorbable.

(b) Classification. Class I.

§ 878.4780 Powered suction pump.

(a) Identification. A powered suction pump is a portable, AC-powered or compressed air-powered device intended to be used to remove infectious materials from wounds or fluids from a patient’s airway or respiratory support system. The device may be used during surgery in the operating room or at the patient’s bedside. The device may include a microbial filter.

(b) Classification. Class II.

§ 878.4800 Manual surgical instrument for general use.

(a) Identification. A manual surgical instrument for general use is a non-powered, hand-held, or hand-manipulated device, either reusable or disposable, intended to be used in various general surgical procedures. The device includes the applicator, clip applier, biopsy brush, manual dermabrasion brush, scrub brush, cannula, ligature carrier, chisel, clamp, contractor, curette, cutter, dissector, elevator, skin graft expander, file, forceps, gouge, instrument guide, needle guide, hammer, hemostat, amputation hook, ligature passing and knot-tying instrument, knife, blood lancet, mallet, disposable or reusable aspiration and injection needle, osteotome, pliers, rasp, retainer, retractor, saw, scalpel blade, scalpel handle, one-piece scalpel, snare, spatula, stapler, disposable or reusable stripper, stylet, suturing apparatus for the stomach and intestine, measuring tape, and calipers. A surgical instrument that has specialized uses in a specific medical specialty is classified in separate regulations in parts 868 through 892.

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


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

(a) Identification. (1) A carbon dioxide laser for use in general surgery and in dermatology is a laser device intended to cut, destroy, or remove tissue by light energy emitted by carbon dioxide.

(2) An argon laser for use in dermatology is a laser device intended to destroy or coagulate tissue by light energy emitted by argon.

(b) Classification. (1) Class II.

(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.

[53 FR 23872, June 24, 1988, as amended at 61 FR 1123, Jan. 16, 1996]

§ 878.4820 Surgical instrument motors and accessories/attachments.

(a) Identification. Surgical instrument motors and accessories are AC-powered, battery-powered, or air-powered devices intended for use during surgical procedures to provide power to operate various accessories or attachments to cut hard tissue or bone and soft tissue. Accessories or attachments may include a bur, chisel (osteotome), dermabrasion brush, dermatome, drill...
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bit, hammerhead, pin driver, and saw blade.
(b) Classification. Class I.
[55 FR 48440, Nov. 20, 1990]

§ 878.4830 Absorbable surgical gut suture.

(a) Identification. An absorbable surgical gut suture, both plain and chromic, is an absorbable, sterile, flexible thread prepared from either the serosal connective tissue layer of beef (bovine) or the submucosal fibrous tissue of sheep (ovine) intestine, and is intended for use in soft tissue approximation.
(b) Classification. Class I.
[55 FR 48440, Nov. 20, 1990]

§ 878.4930 Suture retention device.

(a) Identification. A suture retention device is a device, such as a retention bridge, a surgical button, or a suture bolster, intended to aid wound healing by distributing suture tension over a larger area in the patient.
(b) Classification. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.
[54 FR 50736, Dec. 11, 1989]

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

(a) Identification. A manual operating table and accessories and a manual operating chair and accessories are non-powered devices, usually with movable components, intended to be used to support a patient during diagnostic examinations or surgical procedures.
(b) Classification. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

§ 878.4960 Operating tables and accessories and operating chairs and accessories.

(a) Identification. Operating tables and accessories and operating chairs and accessories are AC-powered or air-powered devices, usually with movable components, intended for use during diagnostic examinations or surgical procedures to support and position a patient.
(b) Classification. Class I.
[55 FR 48440, Nov. 20, 1990]

§ 878.5000 Nonabsorbable poly(ethylene terephthalate) surgical suture.

(a) Identification. Nonabsorbable poly(ethylene terephthalate) surgical suture is a multifilament, nonabsorbable, sterile, flexible thread prepared from fibers of high molecular weight, long-chain, linear polyesters having recurrent aromatic rings as an integral component and is indicated for use in soft tissue approximation. The poly(ethylene terephthalate) surgical suture meets U.S.P. requirements as described in the U.S.P. Monograph for Nonabsorbable Surgical Sutures; it may be provided uncoated or coated; and it may be undyed or dyed with an appropriate FDA listed color additive. Also, the suture may be provided with or without a standard needle attached.
(b) Classification. Class II.
[56 FR 24685, May 31, 1991]

§ 878.5010 Nonabsorbable polypropylene surgical suture.

(a) Identification. Nonabsorbable polypropylene surgical suture is a monofilament, nonabsorbable, sterile, flexible thread prepared from long-chain polyolefin polymer known as polypropylene and is indicated for use in soft tissue approximation. The polypropylene surgical suture meets United States Pharmacopeia (U.S.P.) requirements as described in the U.S.P. Monograph for Nonabsorbable Surgical Sutures; it may be undyed or dyed with an FDA approved color additive; and the suture may be provided with or without a standard needle attached.
(b) Classification. Class II.
[56 FR 24685, May 31, 1991]

§ 878.5020 Nonabsorbable polyamide surgical suture.

(a) Identification. Nonabsorbable polyamide surgical suture is a nonabsorbable, sterile, flexible thread prepared from long-chain aliphatic polymers Nylon 6 and Nylon 6,6 and is indicated for use in soft tissue approximation.
The polyamide surgical suture meets United States Pharmacopeia (U.S.P.) requirements as described in the U.S.P. monograph for nonabsorbable surgical sutures; it may be monofilament or multifilament in form; it may be provided uncoated or coated; and it may be undyed or dyed with an appropriate FDA listed color additive. Also, the suture may be provided with or without a standard needle attached.

(b) Classification. Class II.

[56 FR 24685, May 31, 1991]

§ 878.5030 Natural nonabsorbable silk surgical suture.

(a) Identification. Natural nonabsorbable silk surgical suture is a nonabsorbable, sterile, flexible multifilament thread composed of an organic protein called fibroin. This protein is derived from the domesticated species Bombyx mori (B. mori) of the family Bombycidae. Natural nonabsorbable silk surgical suture is indicated for use in soft tissue approximation. Natural nonabsorbable silk surgical suture meets the United States Pharmacopeia (U.S.P.) monograph requirements for Nonabsorbable Surgical Suture (class I). Natural nonabsorbable silk surgical suture may be braided or twisted; it may be provided uncoated or coated; and it may be undyed or dyed with an FDA listed color additive.

(b) Classification. Class II (special controls).

[58 FR 57558, Oct. 26, 1993]

§ 878.5040 Suction lipoplasty system.

(a) Identification. A suction lipoplasty system is a device intended for aesthetic body contouring. The device consists of a powered suction pump (containing a microbial filter on the exhaust and a microbial in-line filter in the connecting tubing between the collection bottle and the safety trap), collection bottle, cannula, and connecting tube. The microbial filters, tubing, collection bottle, and cannula must be capable of being changed between patients. The powered suction pump has a motor with a minimum of 1/3 horsepower, a variable vacuum range from 0 to 29.9 inches of mercury, vacuum control valves to regulate the vacuum with accompanying vacuum gauges, a single or double rotary vane (with or without oil), a single or double diaphragm, a single or double piston, and a safety trap.

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

[53 FR 23872, June 24, 1988, as amended at 61 FR 1123, Jan. 16, 1996]

§ 878.5350 Needle-type epilator.

(a) Identification. A needle-type epilator is a device intended to destroy the dermal papilla of a hair by applying electric current at the tip of a fine needle that has been inserted close to the hair shaft, under the skin, and into the dermal papilla. The electric current may be high-frequency AC current, high-frequency AC combined with DC current, or DC current only.

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

[63 FR 7705, Feb. 17, 1998]

Subpart F—Therapeutic Devices

§ 878.5360 Tweezer-type epilator.

(a) Identification. The tweezer-type epilator is an electrical device intended to remove hair. The energy provided at the tip of the tweezer used to remove hair may be radio frequency, galvanic (direct current), or a combination of radio frequency and galvanic energy.

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

[63 FR 7060, Oct. 26, 1998]
§ 878.5650 Topical oxygen chamber for extremities.

(a) Identification. A topical oxygen chamber for extremities is a device intended to surround hermetically a patient’s limb and apply humidified oxygen topically at a pressure slightly greater than atmospheric pressure to aid healing of chronic skin ulcers or bed sores.

(b) Classification. Class III.

(c) Date PMA or notice of completion of a PDP is required. No effective date has been established of the requirement for premarket approval. See §878.3.

§ 878.5900 Nonpneumatic tourniquet.

(a) Identification. A nonpneumatic tourniquet is a device consisting of a strap or tubing intended to be wrapped around a patient’s limb and tightened to reduce circulation.

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


§ 878.5910 Pneumatic tourniquet.

(a) Identification. A pneumatic tourniquet is an air-powered device consisting of a pressure-regulating unit, connecting tubing, and an inflatable cuff. The cuff is intended to be wrapped around a patient’s limb and inflated to reduce or totally occlude circulation during surgery.

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

[53 FR 23872, June 24, 1988, as amended at 61 FR 1123, Jan. 16, 1996]

PART 880—GENERAL HOSPITAL AND PERSONAL USE DEVICES

Subpart A—General Provisions

Sec. 880.1 Scope.

880.3 Effective dates of requirement for premarket approval.

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

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Subpart B [Reserved]

Subpart C—General Hospital and Personal Use Monitoring Devices

880.2220 Liquid crystal forehead temperature strip.

880.2400 Bed-patient monitor.

880.2420 Electronic monitor for gravity flow infusion systems.

880.2460 Electrically powered spinal fluid pressure monitor.

880.2500 Spinal fluid manometer.

880.2700 Stand-on patient scale.

880.2720 Patient scale.

880.2740 Surgical sponge scale.

880.2800 Sterilization process indicator.

880.2900 Clinical color change thermometer.

880.2910 Clinical electronic thermometer.

880.2920 Clinical mercury thermometer.

880.2930 Apgar timer.

Subparts D—E [Reserved]

Subpart F—General Hospital and Personal Use Therapeutic Devices

880.5025 I.V. container.

880.5045 Medical recirculating air cleaner.

880.5075 Elastic bandage.

880.5100 Liquid bandage.

880.5110 AC-powered adjustable hospital bed.

880.5110 Hydraulic adjustable hospital bed.

880.5120 Manual adjustable hospital bed.

880.5130 Infant radiant warmer.

880.5140 Pediatric hospital bed.

880.5150 Nonpowered flotation therapy mattress.

880.5160 Therapeutic medical binder.

880.5180 Burn sheet.

880.5200 Intravascular catheter.

880.5200 Intravascular catheter securement device.

880.5246 Medical adhesive tape and adhesive bandage.

880.5270 Neonatal eye pad.

880.5300 Medical absorbent fiber.

880.5400 Neonatal incubator.

880.5410 Neonatal transport incubator.

880.5420 Pressure infusor for an I.V. bag.

880.5430 Nonelectrically powered fluid injector.

880.5440 Intravascular administration set.

880.5450 Patient care reverse isolation chamber.

880.5475 Jet lavage.

880.5500 AC-powered patient lift.

880.5510 Non-AC-powered patient lift.

880.5550 Alternating pressure air flotation mattress.

880.5560 Temperature regulated water mattress.

880.5570 Hypodermic single lumen needle.

880.5580 Acupuncture needle.

880.5630 Nipple shield.

880.5640 Lamb feeding nipple.

880.5680 Pediatric position holder.

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