

**§ 878.5035**

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]

**§ 878.5035 Nonabsorbable expanded polytetrafluoroethylene surgical suture.**

(a) *Identification*. Nonabsorbable expanded polytetrafluoroethylene (ePTFE) surgical suture is a monofilament, nonabsorbable, sterile, flexible thread prepared from ePTFE and is intended for use in soft tissue approximation and ligation, including cardiovascular surgery. It may be undyed or dyed with an approved color additive and may be provided with or without an attached needle(s).

(b) *Classification*. Class II (special controls). FDA recognized consensus standards and device-specific labeling:

(1) United States Pharmacopoeia (USP) 21:

(i) Monograph for Nonabsorbable Surgical Sutures;

(ii) Sutures—Diameter <861>;

(iii) Sutures Needle Attachment <871>; and

(iv) Tensile Strength <881>.

(2) Labeling:

(i) Contraindication: “This device is contraindicated for use in ophthalmic and neural tissues and for use in microsurgery.”

(ii) “For Single Use Only.”

(iii) If the marketed suture has a different diameter than the diameter specified in USP 21—Suture Diameter <861>, then a tabular comparison of its diameter and USP sizes should be included in the labeling.

[65 FR 20735, Apr. 18, 2000]

**§ 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

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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 (special controls). Consensus standards and labeling restrictions.

[63 FR 7705, Feb. 17, 1998]

**Subpart F—Therapeutic Devices**

**§ 878.5070 Air-handling apparatus for a surgical operating room.**

(a) *Identification*. Air-handling apparatus for a surgical operating room is a device intended to produce a directed, nonturbulent flow of air that has been filtered to remove particulate matter and microorganisms to provide an area free of contaminants to reduce the possibility of infection in the patient.

(b) *Classification*. Class II.

**§ 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.

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

**§ 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 57060, 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.

[53 FR 23872, June 24, 1988, as amended at 54 FR 13828, Apr. 5, 1989; 59 FR 63010, Dec. 7, 1994]

**§ 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).

**Subpart B [Reserved]**

**Subpart C—General Hospital and Personal Use Monitoring Devices**

880.2200 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.

880.5090 Liquid bandage.

880.5100 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.

880.5210 Intravascular catheter securement device.

880.5240 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 infuser for an I.V. bag.

880.5430 Nonelectrically powered fluid injector.

880.5440 Intravascular administration set.