

§ 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

21 CFR Ch. I (4–1–01 Edition)

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