

§ 878.5030

21 CFR Ch. I (4-1-98 Edition)

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 (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.* A tweezer-type epilator is an electrical device intended for hair removal. The device provides a high-frequency electric current at the tip of a tweezer used for removing hair.

(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.