

§ 878.5020

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]

21 CFR Ch. I (4-1-03 Edition)

§ 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 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