§ 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 Bombbyx 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). The special control for this device is FDA’s “Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA.” See §878.1(e) for the availability of this guidance document.


§ 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). The special control for this device is FDA’s “Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA.” See §878.1(e) for the availability of this guidance document.

[65 FR 20735, Apr. 18, 2000, as amended at 68 FR 32985, June 3, 2003]

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 (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in §878.9.

§ 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 the premarket notification procedures in subpart E of part 807 of this chapter subject to §878.9.

§ 878.5400 Low level laser system for aesthetic use

(a) Identification. A Low Level Laser System for Aesthetic Use is a device using low level laser energy for the disruption of adipocyte cells within the fat layer for the release of fat and lipids from these cells for noninvasive aesthetic use.

(b) Classification. Class II (special controls). The special control for this device is the FDA guidance document entitled “Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Low Level Laser System for Aesthetic Use.” See §878.1(e) for the availability of this guidance document.

§ 878.5650 Topical oxygen chamber for extremities.

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

(b) Classification. Class II (special controls). The special control for this device is FDA’s “Class II Special Controls Guidance: Topical Oxygen Chamber for Extremities.” See §878.1(e) for the availability of this guidance document.

§ 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 (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in §878.9.

§ 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 (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in §878.9.