§ 878.4490 Absorbable hemostatic agent and dressing.

(a) Identification. An absorbable hemostatic agent or dressing is a device intended to produce hemostasis by accelerating the clotting process of blood. It is absorbable.

(b) Classification. Class III.

(c) Date PMA or notice of completion of a PDP is required. As of May 28, 1976, an approval under section 515 of the act is required before this device may be commercially distributed. See §878.3.

§ 878.4493 Absorbable poly(glycolide/ε-lactide) surgical suture.

(a) Identification. An absorbable poly(glycolide/ε-lactide) surgical suture (PGL suture) is an absorbable sterile, flexible strand as prepared and synthesized from homopolymers of glycolide and copolymers made from 90 percent glycolide and 10 percent ε-lactide, and is indicated for use in soft tissue approximation. A PGL suture meets United States Pharmacopeia (U.S.P.) requirements as described in the U.S.P. “Monograph for Absorbable Surgical Sutures;” it may be monofilament or multifilament (braided) in form; it may be uncoated or coated; and it may be undyed or dyed with an FDA-approved color additive. Also, the suture may be provided with or without a standard needle attached.

(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.


§ 878.4520 Polytetrafluoroethylene injectable.

(a) Identification. Polytetrafluoroethylene injectable is an injectable paste prosthetic device composed of polytetrafluoroethylene intended to be used to augment or reconstruct a vocal cord.

(b) Classification. Class III.

(c) Date PMA or notice of completion of a PDP is required. As of May 28, 1976, an approval under section 515 of the act is required before this device may be commercially distributed. See §878.3.

§ 878.4580 Surgical lamp.

(a) Identification. A surgical lamp (including a fixture) is a device intended to be used to provide visible illumination of the surgical field or the patient.

(b) Classification. Class II.

§ 878.4590 Focused ultrasound stimulator system for aesthetic use.

(a) Identification. A Focused Ultrasound Stimulator System for Aesthetic Use is a device using focused ultrasound energy to stimulate tissue.