§ 878.4456 Hemostatic device for intraluminal gastrointestinal use.

(a) *Identification.* A hemostatic device for intraluminal gastrointestinal use is a prescription device that is endoscopically applied to the upper and/or lower gastrointestinal tract and is intended to produce hemostasis via absorption of fluid or by other physical means.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) The device must be demonstrated to be biocompatible.

(2) Performance data must support the sterility and pyrogenicity of the device.

(3) Performance data must support the shelf life of the device by demonstrating continued sterility, package integrity, and device functionality over the identified shelf life.

(4) In vivo performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The testing must evaluate the following:

(i) The ability to deliver the hemostatic material to the bleeding site;

(ii) The ability to achieve hemostasis in a clinically relevant model of gastrointestinal bleeding; and

(iii) Safety endpoints, including thromboembolic events, local and systemic toxicity, tissue trauma, gastrointestinal tract obstruction, and bowel distension and perforation.

(5) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be evaluated:

(i) Materials characterization of all components must demonstrate the device meets established specifications, which must include compositional identity and purity, characterization of impurities, physical characteristics, and reactivity with fluids.

(ii) Performance testing must demonstrate the mechanical integrity and functionality of the system used to deliver the device and demonstrate the device meets established specifications, including output pressure for propellant-based systems.

(6) Labeling must include:

(i) Information identifying and explaining how to use the device and its components; and

(ii) A shelf life.

[83 FR 52971, Oct. 19, 2018]

§ 878.4460 Non-powdered surgeon's glove.

(a) *Identification.* A non-powdered surgeon's glove is a device intended to be worn on the hands of operating room personnel to protect a surgical wound from contamination. A non-powdered surgeon's glove does not incorporate powder for purposes other than manufacturing. The final finished glove includes only residual powder from manufacturing.

(b) *Classification.* Class I (general controls).

[53 FR 23872, June 24, 1988, as amended at 66 FR 46952, Sept. 10, 2001; 81 FR 91730, Dec. 19, 2016]

§ 878.4470 Surgeon's gloving cream.

(a) *Identification.* Surgeon's gloving cream is an ointment intended to be used to lubricate the user's hand before putting on a surgeon's glove.

(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.

[53 FR 23872, June 24, 1988, as amended at 59 FR 63010, Dec. 7, 1994; 66 FR 38803, July 25, 2001]

§ 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/l-lactide) surgical suture.

(a) *Identification.* An absorbable poly(glycolide/l-lactide) surgical suture (PGL suture) is an absorbable sterile,