§ 878.4456

§ 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/llactide) surgical suture.

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