(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, flexible strand as prepared and synthesized from homopolymers of glycolide and copolymers made from 90 percent glycolide and 10 percent l-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.

[56 FR 47151, Sept. 18, 1991, as amended at 68 FR 32984, June 3, 2003]

§ 878.4494 Absorbable poly(hydroxybutyrate) surgical suture produced by recombinant DNA technology.

(a) *Identification.* An absorbable poly(hydroxybutyrate) surgical suture is an absorbable surgical suture made of material isolated from prokaryotic cells produced by recombinant deoxyribonucleic acid (DNA) technology. The device is intended for use in general soft tissue approximation and ligation.

(b) *Classification.* Class II (special controls). The special control for this device is the FDA guidance document entitled ''Class II Special Controls Guidance Document: Absorbable Poly(hydroxybutyrate) Surgical Suture Produced by Recombinant DNA Technology.'' For the availability of this guidance document see § 878.1(e).

[72 FR 43146, Aug. 3, 2007]