§ 878.4400 Electrosurgical cutting and coagulation device and accessories.

(a) Identification. An electrosurgical cutting and coagulation device and accessories is a device intended to remove tissue and control bleeding by use of high-frequency electrical current.

(b) Classification. Class II.

§ 878.4410 Low energy ultrasound wound cleaner.

(a) Identification. A low energy ultrasound wound cleaner is a device that uses ultrasound energy to vaporize a solution and generate a mist that is used for the cleaning and maintenance debridement of wounds. Low levels of ultrasound energy may be carried to the wound by the saline mist.

(b) Classification. Class II (special 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.

§ 878.4460 Surgeon’s glove.

(a) Identification. A surgeon’s glove is a device made of natural or synthetic rubber intended to be worn by operating room personnel to protect a surgical wound from contamination. The lubricating or dusting powder used in the glove is excluded.

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

§ 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.

§ 878.4480 Absorbable powder for lubricating a surgeon’s glove.

(a) Identification. Absorbable powder for lubricating a surgeon’s glove is a powder made from corn starch that meets the specifications for absorbable powder in the United States Pharmacopeia (U.S.P.) and that is intended to be used to lubricate the surgeon’s hand before putting on a surgeon’s glove. The device is absorbable through biological degradation.

(b) Classification. Class III.