Subpart E—Surgical Devices

§ 886.4070 Powered corneal burr.
(a) Identification. A powered corneal burr is an AC-powered or battery-powered device that is a motor and drilling tool intended to remove rust rings from the cornea of the eye.

(b) Classification. Class I (general controls). When intended only for rust ring removal, the device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 886.9.

§ 886.4100 Radiofrequency electrosurgical cautery apparatus.
(a) Identification. A radiofrequency electrosurgical cautery apparatus is an AC-powered or battery-powered device intended for use during ocular surgery to coagulate tissue or arrest bleeding by a high frequency electric current.

(b) Classification. Class II.

§ 886.4115 Thermal cautery unit.
(a) Identification. A thermal cautery unit is an AC-powered or battery-powered device intended for use during ocular surgery to coagulate tissue or arrest bleeding by heat conducted through a wire tip.

(b) Classification. Class II.

§ 886.4150 Vitreous aspiration and cutting instrument.
(a) Identification. A vitreous aspiration and cutting instrument is an electrically powered device, which may use ultrasound, intended to remove vitreous matter from the vitreous cavity or remove a crystalline lens.

(b) Classification. Class II.

§ 886.4230 Ophthalmic knife test drum.
(a) Identification. An ophthalmic knife test drum is a device intended to test the keenness of ophthalmic surgical knives to determine whether resharpening is needed.

(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 § 886.9. The device is also exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 886.4250 Ophthalmic electrolysis unit.
(a) Identification. An ophthalmic electrolysis unit is an AC-powered or battery-powered device intended to destroy ocular hair follicles by applying a galvanic electrical current.

(b) Classification. Class II for the AC-powered device. The battery-powered device, Class II for the battery-powered device. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9.