Food and Drug Administration, HHS

§ 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.

§ 886.4170 Cryophthalmic unit.

(a) Identification. A cryophthalmic unit is a device that is a probe with a small tip that becomes extremely cold through the controlled use of a refrigerant or gas. The device may be AC-powered. The device is intended to remove cataracts by the formation of an adherent ice ball in the lens, to freeze the eye and adjunct parts for surgical removal of scars, and to freeze tumors.

(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 re-sharpening 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.

§ 886.4250 Ophthalmic electrocautery unit.

(a) Identification. An electrocautery 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.

§ 886.4270 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.

§ 886.4100 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.