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.

§ 886.4230 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.

§ 886.4250 Ophthalmic electrocautery device.

(a) Identification. An ophthalmic electrocautery device is an AC-powered or battery-powered device intended to destroy ooar tissue by heat conducted through a wire tip.

(b) Classification. Class II.