§ 886.4350 Manual ophthalmic surgical instrument.

(a) Identification. A manual ophthalmic surgical instrument is a non-powered, handheld device intended to aid or perform ophthalmic surgical procedures. This generic type of device includes the manual corneal burr, ophthalmic caliper, ophthalmic cannula, eyelid clamp, ophthalmic muscle clamp, iris retractors, or orbital compressor, ophthalmic curette, cystotome, or orbital depressor, lacrymal dilator, erisophake, expressor, ophthalmic forceps, ophthalmic hook, sphere introducer, ophthalmic knife, ophthalmic suturing needle, ophthalmic ring (Flieringa), lacrymal sac rongeur, ophthalmic scissors, enucleating snare, ophthalmic spatula, ophthalmic specula, ophthalmic spoon, ophthalmic spud, trabeculotome or ophthalmic manual trephine.

(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.


§ 886.4350 Ocular surgery irrigation device.

(a) Identification. An ocular surgery irrigation device is a device intended to be suspended over the ocular area during ophthalmic surgery to deliver continuous, controlled irrigation to the surgical field.

(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.