

§ 886.4350

AC-powered device. The battery-powered device is exempt from the pre-market notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9.

[55 FR 48443, Nov. 20, 1990, as amended at 66 FR 38813, July 25, 2001]

§ 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 retractor clip, orbital compressor, ophthalmic curette, cystotome, orbital depressor, lachrymal dilator, erisophake, expressor, ophthalmic forcep, ophthalmic hook, sphere introducer, ophthalmic knife, ophthalmic suturing needle, lachrymal probe, trabeculotomy probe, cornea-sclera punch, ophthalmic retractor, ophthalmic ring (Flieringa), lachrymal 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.

[52 FR 33355, Sept. 2, 1987, as amended at 53 FR 35606, Sept. 14, 1988; 59 FR 63013, Dec. 7, 1994; 60 FR 15872, Mar. 28, 1995; 66 FR 38813, July 25, 2001]

§ 886.4360 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.

[52 FR 33355, Sept. 2, 1987, as amended at 53 FR 35606, Sept. 14, 1988; 59 FR 63013, Dec. 7, 1994; 66 FR 38813, July 25, 2001]

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§ 886.4370 Keratome.

(a) *Identification.* A keratome is an AC-powered or battery-powered device intended to shave tissue from sections of the cornea for a lamellar (partial thickness) transplant.

(b) *Classification.* Class I.

[55 FR 48443, Nov. 20, 1990]

§ 886.4390 Ophthalmic laser.

(a) *Identification.* An ophthalmic laser is an AC-powered device intended to coagulate or cut tissue of the eye, orbit, or surrounding skin by a laser beam.

(b) *Classification.* Class II.

§ 886.4392 Nd:YAG laser for posterior capsulotomy and peripheral iridotomy.

(a) *Identification.* The Nd:YAG laser for posterior capsulotomy and peripheral iridotomy consists of a mode-locked or Q-switched solid state Nd:YAG laser intended for disruption of the posterior capsule or the iris via optical breakdown. The Nd:YAG laser generates short pulse, low energy, high power, coherent optical radiation. When the laser output is combined with focusing optics, the high irradiance at the target causes tissue disruption via optical breakdown. A visible aiming system is utilized to target the invisible Nd:YAG laser radiation on or in close proximity to the target tissue.

(b) *Classification.* Class II (special controls). Design Parameters: Device must emit a laser beam with the following parameters: wavelength = 1064 nanometers; spot size = 50 to 100 micros; pulse width = 3 to 30 nanoseconds; output energy per pulse = 0.5 to 15 millijoules (mJ); repetition rate = 1 to 10 pulses; and total energy = 20 to 120 mJ.

[65 FR 6894, Feb. 11, 2000]

§ 886.4400 Electronic metal locator.

(a) *Identification.* An electronic metal locator is an AC-powered device with probes intended to locate metallic foreign bodies in the eye or eye socket.

(b) *Classification.* Class II.

§ 886.4440 AC-powered magnet.

(a) *Identification.* An AC-powered magnet is an AC-powered device that