

§ 886.1

- 886.1840 Simulatan (including crossed cylinder).
- 886.1850 AC-powered slitlamp biomicroscope.
- 886.1860 Ophthalmic instrument stand.
- 886.1870 Stereoscope.
- 886.1880 Fusion and stereoscopic target.
- 886.1905 Nystagmus tape.
- 886.1910 Spectacle dissociation test system.
- 886.1930 Tonometer and accessories.
- 886.1940 Tonometer sterilizer.
- 886.1945 Transilluminator.

Subpart C [Reserved]

Subpart D—Prosthetic Devices

- 886.3100 Ophthalmic tantalum clip.
- 886.3130 Ophthalmic conformer.
- 886.3200 Artificial eye.
- 886.3300 Absorbable implant (scleral buckling method).
- 886.3320 Eye sphere implant.
- 886.3340 Extraocular orbital implant.
- 886.3400 Keratoprosthesis.
- 886.3600 Intraocular lens.
- 886.3800 Scleral shell.
- 886.3920 Aqueous shunt.

Subpart E—Surgical Devices

- 886.4070 Powered corneal burr.
- 886.4100 Radiofrequency electrosurgical cautery apparatus.
- 886.4115 Thermal cautery unit.
- 886.4150 Vitreous aspiration and cutting instrument.
- 886.4170 Cryophthalmic unit.
- 886.4230 Ophthalmic knife test drum.
- 886.4250 Ophthalmic electrolysis unit.
- 886.4270 Intraocular gas.
- 886.4275 Intraocular fluid.
- 886.4280 Intraocular pressure measuring device.
- 886.4300 Intraocular lens guide.
- 886.4335 Operating headlamp.
- 886.4350 Manual ophthalmic surgical instrument.
- 886.4360 Ocular surgery irrigation device.
- 886.4370 Keratome.
- 886.4390 Ophthalmic laser.
- 886.4392 Nd:YAG laser for posterior capsulotomy and peripheral iridotomy.
- 886.4400 Electronic metal locator.
- 886.4440 AC-powered magnet.
- 886.4445 Permanent magnet.
- 886.4570 Ophthalmic surgical marker.
- 886.4610 Ocular pressure applicator.
- 886.4670 Phacofragmentation system.
- 886.4690 Ophthalmic photocoagulator.
- 886.4750 Ophthalmic eye shield.
- 886.4770 Ophthalmic operating spectacles (loupes).
- 886.4790 Ophthalmic sponge.
- 886.4855 Ophthalmic instrument table.

21 CFR Ch. I (4–1–08 Edition)

Subpart F—Therapeutic Devices

- 886.5100 Ophthalmic beta radiation source.
- 886.5120 Low-power binocular loupe.
- 886.5420 Contact lens inserter/remover.
- 886.5540 Low-vision magnifier.
- 886.5600 Ptosis crutch.
- 886.5800 Ophthalmic bar reader.
- 886.5810 Ophthalmic prism reader.
- 886.5820 Closed-circuit television reading system.
- 886.5840 Magnifying spectacles.
- 886.5842 Spectacle frame.
- 886.5844 Prescription spectacle lens.
- 886.5850 Sunglasses (nonprescription).
- 886.5870 Low-vision telescope.
- 886.5900 Electronic vision aid.
- 886.5910 Image intensification vision aid.
- 886.5915 Optical vision aid.
- 886.5916 Rigid gas permeable contact lens.
- 886.5918 Rigid gas permeable contact lens care products.
- 886.5925 Soft (hydrophilic) contact lens.
- 886.5928 Soft (hydrophilic) contact lens care products.
- 886.5933 [Reserved]

AUTHORITY: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

SOURCE: 52 FR 33355, Sept. 2, 1987, unless otherwise noted.

Subpart A—General Provisions

§ 886.1 Scope.

(a) This part sets forth the classification of ophthalmic devices intended for human use that are in commercial distribution.

(b) The identification of a device in a regulation in this part is not a precise description of every device that is, or will be, subject to the regulation. A manufacturer who submits a pre-market notification submission for a device under part 807 cannot show merely that the device is accurately described by the section title and identification provision of a regulation in this part but shall state why the device is substantially equivalent to other devices, as required by § 807.87.

(c) To avoid duplicative listings, an ophthalmic device that has two or more types of uses (e.g., used both as a diagnostic device and as a therapeutic device) is listed in one subpart only.

(d) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21 unless otherwise noted.