

testing, and clinical testing). The device, when it is phosphate-buffered saline used for washing, and short-term handling and manipulation of gametes and embryos; culture oil used as an overlay for culture media containing gametes and embryos; and water for assisted reproduction applications, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 884.9.

[63 FR 48436, Sept. 10, 1998, as amended at 85 FR 44188, July 22, 2020]

**§ 884.6190 Assisted reproductive microscopes and microscope accessories.**

(a) *Identification.* Assisted reproduction microscopes and microscope accessories (excluding microscope stage warmers, which are classified under assisted reproduction accessories) are optical instruments used to enlarge images of gametes or embryos. Variations of microscopes and accessories used for these purposes would include phase contrast microscopes, dissecting microscopes and inverted stage microscopes.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 884.9.

[63 FR 48436, Sept. 10, 1998, as amended at 64 FR 62977, Nov. 18, 1999; 66 FR 38809, July 25, 2001]

**§ 884.6195 Assisted Reproduction Embryo Image Assessment System.**

(a) *Identification.* An Assisted Reproduction Embryo Image Assessment System is a prescription device that is designed to obtain and analyze light microscopy images of developing embryos. This device provides information to aid in the selection of embryo(s) for transfer when there are multiple embryos deemed suitable for transfer or freezing.

(b) *Classification.* Class II (special controls). The special control(s) for this device are:

(1) Clinical performance testing must demonstrate a reasonable assurance of safety and effectiveness of the device to predict embryo development. Classification performance (sensitivity and

specificity) and predictive accuracy (Positive Predictive Value and Negative Predictive Value) must be assessed at the subject and embryo levels.

(2) Software validation, verification, and hazard analysis must be provided.

(3) Non-clinical performance testing data must demonstrate the performance characteristics of the device. Testing must include the following:

(i) Total light exposure and output testing;

(ii) A safety analysis must be performed based on maximum (worst-case) light exposure to embryos, which also includes the safety of the light wavelength(s) emitted by the device;

(iii) Simulated-use testing;

(iv) Mouse Embryo Assay testing to assess whether device operation impacts growth and development of mouse embryos to the blastocyst stage;

(v) Cleaning and disinfection validation of reusable components;

(vi) Package integrity and transit testing;

(vii) Hardware fail-safe validation;

(viii) Electrical equipment safety and electromagnetic compatibility testing; and

(ix) Prediction algorithm reproducibility.

(4) Labeling must include the following:

(i) A detailed summary of clinical performance testing, including any adverse events;

(ii) Specific instructions, warnings, precautions, and training needed for safe use of the device

(iii) Appropriate electromagnetic compatibility information;

(iv) Validated methods and instructions for cleaning and disinfection of reusable components; and

(v) Information identifying compatible cultureware and explain how they are used with the device.

[80 FR 10332, Feb. 26, 2015]

**§ 884.6200 Assisted reproduction laser system.**

(a) *Identification.* The assisted reproduction laser system is a device that images, targets, and controls the power and pulse duration of a laser beam used to ablate a small tangential hole in, or

to thin, the zona pellucida of an embryo for assisted hatching or other assisted reproduction procedures.

(b) *Classification.* Class II (special controls). The special control is FDA's guidance document entitled "Class II Special Controls Guidance Document: Assisted Reproduction Laser Systems." See §884.1(e) for the availability of this guidance document.

[69 FR 77624, Dec. 28, 2004]

## PART 886—OPHTHALMIC DEVICES

### Subpart A—General Provisions

Sec.

- 886.1 Scope.
- 886.3 Effective dates of requirement for pre-market approval.
- 886.9 Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).

### Subpart B—Diagnostic Devices

- 886.1040 Ocular esthesiometer.
- 886.1050 Adaptometer (biophotometer).
- 886.1070 Anomaloscope.
- 886.1090 Haidinger brush.
- 886.1100 Retinal diagnostic software device.
- 886.1120 Ophthalmic camera.
- 886.1140 Ophthalmic chair.
- 886.1150 Visual acuity chart.
- 886.1160 Color vision plate illuminator.
- 886.1170 Color vision tester.
- 886.1190 Distometer.
- 886.1200 Optokinetic drum.
- 886.1220 Corneal electrode.
- 886.1250 Euthyscope.
- 886.1270 Exophthalmometer.
- 886.1290 Fixation device.
- 886.1300 Afterimage flasher.
- 886.1320 Fornixscope.
- 886.1330 Amsler grid.
- 886.1340 Haploscope.
- 886.1342 Strabismus detection device.
- 886.1350 Keratoscope.
- 886.1360 Visual field laser instrument.
- 886.1375 Bagolini lens.
- 886.1380 Diagnostic condensing lens.
- 886.1385 Polymethylmethacrylate (PMMA) diagnostic contact lens.
- 886.1390 Flexible diagnostic Fresnel lens.
- 886.1395 Diagnostic Hruby fundus lens.
- 886.1400 Maddox lens.
- 886.1405 Ophthalmic trial lens set.
- 886.1410 Ophthalmic trial lens clip.
- 886.1415 Ophthalmic trial lens frame.
- 886.1420 Ophthalmic lens gauge.
- 886.1425 Lens measuring instrument.
- 886.1430 Ophthalmic contact lens radius measuring device.
- 886.1435 Maxwell spot.
- 886.1450 Corneal radius measuring device.

- 886.1460 Stereopsis measuring instrument.
- 886.1500 Headband mirror.
- 886.1510 Eye movement monitor.
- 886.1570 Ophthalmoscope.
- 886.1605 Perimeter.
- 886.1630 AC-powered photostimulator.
- 886.1640 Ophthalmic preamplifier.
- 886.1650 Ophthalmic bar prism.
- 886.1655 Ophthalmic Fresnel prism.
- 886.1660 Gonioscopic prism.
- 886.1665 Ophthalmic rotary prism.
- 886.1670 Ophthalmic isotope uptake probe.
- 886.1680 Ophthalmic projector.
- 886.1690 Pupillograph.
- 886.1700 Pupillometer.
- 886.1750 Skiascopic rack.
- 886.1760 Ophthalmic refractometer.
- 886.1770 Manual refractor.
- 886.1780 Retinoscope.
- 886.1790 Nearpoint ruler.
- 886.1800 Schirmer strip.
- 886.1810 Tangent screen (campimeter).
- 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.
- 886.1925 Diurnal pattern recorder 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 electro-surgical cautery apparatus.
- 886.4115 Thermal cautery unit.
- 886.4150 Vitreous aspiration and cutting instrument.
- 886.4155 Scleral plug.
- 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.