

(b) *Classification.* Class II (special controls) (mouse embryo assay information, endotoxin testing, sterilization validation, design specifications, labeling requirements, biocompatibility testing, and clinical testing).

§ 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]

§ 884.6200 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 premarket approval.

886.9 Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).

Subpart B—Diagnostic Devices

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 886.1050 Adaptometer (biophotometer).
 886.1070 Anomaloscope.
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 886.1120 Ophthalmic camera.
 886.1140 Ophthalmic chair.
 886.1150 Visual acuity chart.
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 886.1200 Optokinetic drum.
 886.1220 Corneal electrode.
 886.1250 Euthyscope.
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 886.1320 Fornixscope.
 886.1330 Amsler grid.
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 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.
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 886.1840 Simulatan (including crossed cylinder).