

§ 884.6170

vessels that come into physical contact with gametes, embryos or tissue culture media.

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

§ 884.6170 Assisted reproduction water and water purification systems.

(a) *Identification.* Assisted reproduction water purification systems are devices specifically intended to generate high quality, sterile, pyrogen-free water for reconstitution of media used for aspiration, incubation, transfer or storage of gametes or embryos for in vitro fertilization (IVF) or other assisted reproduction procedures. These devices may also be intended as the final rinse for labware or other assisted reproduction devices that will contact the gametes or embryos. These devices also include bottled water ready for reconstitution available from a vendor that is specifically intended for reconstitution of media used for aspiration, incubation, transfer, or storage of gametes or embryos for IVF or other assisted reproduction procedures.

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

§ 884.6180 Reproductive media and supplements.

(a) *Identification.* Reproductive media and supplement are products that are used for assisted reproduction procedures. Media include liquid and powder versions of various substances that come in direct physical contact with human gametes or embryos (including water, acid solutions used to treat gametes or embryos, rinsing solutions, sperm separation media, supplements, or oil used to cover the media) for the purposes of preparation, maintenance, transfer or storage. Supplements are specific reagents added to media to enhance specific properties of the media (e.g., proteins, sera, antibiotics, etc.).

(b) *Classification.* Class II (special controls) (mouse embryo assay infor-

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mation, 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 1. This device is exempt from the premarket notification procedures in subpart E of part 807 of chapter subject to limitation in § 884.9.

[63 FR 48436, Sept. 10, 1998, as amended at 64 FR 62977, Nov. 18, 1999]

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

- 886.1040 Ocular esthesiometer.
- 886.1050 Adaptometer (biophotometer).
- 886.1070 Anomaloscope.
- 886.1090 Haidlinger brush.
- 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.
- 886.1350 Keratoscope.
- 886.1360 Visual field laser instrument.