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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

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Subpart B—Diagnostic Devices

Subpart C [Reserved]

Subpart D—Prosthetic Devices

Subpart E—Surgical Devices