§ 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.

§ 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 §884.11(e) for the availability of this guidance document.


PART 886—OPHTHALMIC DEVICES

Subpart A—General Provisions

§ 886.1 Scope.

§ 886.3 Effective dates of requirement for premarket approval.