

Food and Drug Administration, HHS

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of this chapter, subject to the limitations in § 884.9.

[45 FR 12684-12720, Feb. 26, 1980, as amended at 54 FR 25052, June 12, 1989; 66 FR 38809, July 25, 2001]

§ 884.5940 Powered vaginal muscle stimulator for therapeutic use.

(a) *Identification.* A powered vaginal muscle stimulator is an electrically powered device designed to stimulate directly the muscles of the vagina with pulsating electrical current. This device is intended and labeled for therapeutic use in increasing muscular tone and strength in the treatment of sexual dysfunction. This generic type of device does not include devices used to treat urinary incontinence.

(b) *Classification.* Class III (premarket approval).

(c) *Date PMA or notice of completion of a PDP is required.* A PMA or a notice of completion of a PDP for a device is required to be filed with the Food and Drug Administration on or before July 12, 2000, for any powered vaginal muscle stimulator for therapeutic use that was in commercial distribution before May 28, 1976, or that has, on or before July 12, 2000, been found to be substantially equivalent to a powered vaginal muscle stimulator that was in commercial distribution before May 28, 1976. Any other powered vaginal muscle stimulator for therapeutic use shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

[45 FR 12684-12720, Feb. 26, 1980, as amended at 52 FR 17741, May 11, 1987; 65 FR 19834, Apr. 13, 2000]

§ 884.5960 Genital vibrator for therapeutic use.

(a) *Identification.* A genital vibrator for therapeutic use is an electrically operated device intended and labeled for therapeutic use in the treatment of sexual dysfunction or as an adjunct to Kegel's exercise (tightening of the muscles of the pelvic floor to increase muscle tone).

(b) *Classification.* Class II (performance standards).

§ 884.5970 Clitoral engorgement device.

(a) *Identification.* A clitoral engorgement device is designed to apply a vacuum to the clitoris. It is intended for use in the treatment of female sexual arousal disorder.

(b) *Classification.* Class II (special controls). The special control is a guidance document entitled: "Guidance for Industry and FDA Reviewers: Class II Special Controls Guidance Document for Clitoral Engorgement Devices."

[65 FR 47306, Aug. 2, 2000]

Subpart G—Assisted Reproduction Devices

SOURCE: 63 FR 48436, Sept. 10, 1998, unless otherwise noted.

§ 884.6100 Assisted reproduction needles.

(a) *Identification.* Assisted reproduction needles are devices used in in vitro fertilization (IVF), gamete intrafallopian transfer (GIFT), or other assisted reproduction procedures to obtain gametes from the body or introduce gametes, zygote(s), preembryo(s) and/or embryo(s) into the body. This generic type of device may include a single or double lumen needle and component parts, including needle guides, such as those used with ultrasound.

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

§ 884.6110 Assisted reproduction catheters.

(a) *Identification.* Assisted reproduction catheters are devices used in in vitro fertilization (IVF), gamete intrafallopian transfer (GIFT), or other assisted reproduction procedures to introduce or remove gametes, zygote(s), preembryo(s), and/or embryo(s) into or from the body. This generic type of device may include catheters, cannulae, introducers, dilators, sheaths, stylets, and component parts.

(b) *Classification.* Class II (special controls) (mouse embryo assay information, endotoxin testing, sterilization

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validation, design specifications, labeling requirements, biocompatibility testing, and clinical testing).

§ 884.6120 Assisted reproduction accessories.

(a) *Identification.* Assisted reproduction accessories are a group of devices used during assisted reproduction procedures, in conjunction with assisted reproduction needles and/or assisted reproduction catheters, to aspirate, incubate, infuse, and/or maintain temperature. This generic type of device may include:

(1) Powered aspiration pumps used to provide low flow, intermittent vacuum for the aspiration of eggs (ova).

(2) Syringe pumps (powered or manual) used to activate a syringe to infuse or aspirate small volumes of fluid during assisted reproduction procedures.

(3) Collection tube warmers, used to maintain the temperature of egg (oocyte) collection tubes at or near body temperature. A dish/plate/microscope stage warmer is a device used to maintain the temperature of the egg (oocyte) during manipulation.

(4) Embryo incubators, used to store and preserve gametes and/or embryos at or near body temperature.

(5) Cryopreservation instrumentation and devices, used to contain, freeze, and maintain gametes and/or embryos at an appropriate freezing temperature.

(b) *Classification.* Class II (special controls) (design specifications, labeling requirements, and clinical testing).

§ 884.6130 Assisted reproduction microtools.

(a) *Identification.* Assisted reproduction microtools are pipettes or other devices used in the laboratory to denude, micromanipulate, hold, or transfer human gametes or embryos for assisted hatching, intracytoplasmic sperm injection (ICSI), or other assisted reproduction methods.

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

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§ 884.6140 Assisted reproduction micropipette fabrication instruments.

(a) *Identification.* Assisted reproduction micropipette fabrication devices are instruments intended to pull, bevel, or forge a micropipette or needle for intracytoplasmic sperm injection (ICSI), in vitro fertilization (IVF) or other similar assisted reproduction procedures.

(b) *Classification.* Class II (special controls) (design specifications, labeling requirements, and clinical testing).

§ 884.6150 Assisted reproduction micromanipulators and microinjectors.

(a) *Identification.* Assisted reproduction micromanipulators are devices intended to control the position of an assisted reproduction microtool. Assisted reproduction microinjectors are any device intended to control aspiration or expulsion of the contents of an assisted reproduction microtool.

(b) *Classification.* Class II (special controls) (design specifications, labeling requirements, and clinical testing).

§ 884.6160 Assisted reproduction labware.

(a) *Identification.* Assisted reproduction labware consists of laboratory equipment or supplies intended to prepare, store, manipulate, or transfer human gametes or embryos for in vitro fertilization (IVF), gamete intrafallopian transfer (GIFT), or other assisted reproduction procedures. These include syringes, IVF tissue culture dishes, IVF tissue culture plates, pipette tips, dishes, plates, and other 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