

§ 884.5900

materials) or those with added antimicrobial agents or other drugs.

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

§ 884.5900 Therapeutic vaginal douche apparatus.

(a) *Identification.* A therapeutic vaginal douche apparatus is a device that is a bag or bottle with tubing and a nozzle. The apparatus does not include douche solutions. The apparatus is intended and labeled for use in the treatment of medical conditions except it is not for contraceptive use. After filling the therapeutic vaginal douche apparatus with a solution, the patient uses the device to direct a stream of solution into the vaginal cavity.

(b) *Classification.* (1) Class II (performance standards).

(2) Class I if the device is operated by gravity feed. Devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 884.9.

[45 FR 12684-12720, Feb. 26, 1980, as amended at 61 FR 1124, Jan. 16, 1996; 66 FR 38809, July 25, 2001]

§ 884.5920 Vaginal insufflator.

(a) *Identification.* A vaginal insufflator is a device used to treat vaginitis by introducing medicated powder from a hand-held bulb into the vagina through an open speculum.

(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.

[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.

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(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.