

§ 876.5270

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(2) Class I (general controls). For a urine collector and accessories not intended to be connected to an indwelling catheter, subject to the limitations in § 876.9. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

[48 FR 53023, Nov. 23, 1983, as amended at 63 FR 59228, Nov. 3, 1998; 65 FR 2317, Jan. 14, 2000; 66 FR 38802, July 25, 2001]

§ 876.5270 **Implanted electrical urinary continence device.**

(a) *Identification.* An implanted electrical urinary device is a device intended for treatment of urinary incontinence that consists of a receiver implanted in the abdomen with electrodes for pulsed-stimulation that are implanted either in the bladder wall or in the pelvic floor, and a battery-powered transmitter outside the body.

(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 is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any implanted electrical urinary continence device that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to an implanted electrical urinary continence device that was in commercial distribution before May 28, 1976. Any other implanted electrical urinary continence device shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

[48 FR 53023, Nov. 23, 1983, as amended at 52 FR 17738, May 11, 1987; 61 FR 50707, Sept. 27, 1996]

§ 876.5280 **Implanted mechanical/hydraulic urinary continence device.**

(a) *Identification.* An implanted mechanical/hydraulic urinary continence device is a device used to treat urinary incontinence by the application of continuous or intermittent pressure to oc-

clude the urethra. The totally implanted device may consist of a static pressure pad, or a system with a container of radiopaque fluid in the abdomen and a manual pump and valve under the skin surface that is connected by tubing to an adjustable pressure pad or to a cuff around the urethra. The fluid is pumped as needed from the container to inflate the pad or cuff to pass on the urethra.

(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 is required to be filed with the Food and Drug Administration on or before December 26, 2000, for any implanted mechanical/hydraulic urinary continence device that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 2000, been found to be substantially equivalent to an implanted mechanical/hydraulic urinary continence device that was in commercial distribution before May 28, 1976. Any other implanted mechanical/hydraulic urinary continence device shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

[48 FR 53023, Nov. 23, 1983, as amended at 52 FR 17738, May 11, 1987; 65 FR 57731, Sept. 26, 2000]

§ 876.5310 **Nonimplanted, peripheral electrical continence device.**

(a) *Identification.* A nonimplanted, peripheral electrical continence device is a device that consists of an electrode that is connected by an electrical cable to a battery-powered pulse source. The electrode is placed onto or inserted into the body at a peripheral location and used to stimulate the nerves associated with pelvic floor function to maintain urinary continence. When necessary, the electrode may be removed by the user.

(b) *Classification.* Class II, subject to the following special controls:

(1) That sale, distribution, and use of this device are restricted to prescription use in accordance with § 801.109 of this chapter.

(2) That the labeling must bear all information required for the safe and effective use of the device as outlined in

§ 801.109(c) of this chapter, including a detailed summary of the clinical information upon which the instructions are based.

[65 FR 18237, Apr. 7, 2000]

§ 876.5320 Nonimplanted electrical continence device.

(a) *Identification.* A nonimplanted electrical continence device is a device that consists of a pair of electrodes on a plug or a pessary that are connected by an electrical cable to a battery-powered pulse source. The plug or pessary is inserted into the rectum or into the vagina and used to stimulate the muscles of the pelvic floor to maintain urinary or fecal continence. When necessary, the plug or pessary may be removed by the user. This device excludes an AC-powered nonimplanted electrical continence device and the powered vaginal muscle stimulator for therapeutic use (§ 884.5940).

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

§ 876.5365 Esophageal dilator.

(a) *Identification.* An esophageal dilator is a device that consists of a cylindrical instrument that may be hollow and weighted with mercury or a metal olive-shaped weight that slides on a guide, such as a string or wire and is used to dilate a stricture of the esophagus. This generic type of device includes esophageal or gastrointestinal bougies and the esophageal dilator (metal olive).

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

§ 876.5450 Rectal dilator.

(a) *Identification.* A rectal dilator is a device designed to dilate the anal sphincter and canal when the size of the anal opening may interfere with its function or the passage of an examining instrument.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 876.9.

[48 FR 53023, Nov. 23, 1983, as amended at 61 FR 1122, Jan. 16, 1996; 66 FR 38802, July 25, 2001]

§ 876.5470 Ureteral dilator.

(a) *Identification.* A ureteral dilator is a device that consists of a specially shaped catheter or bougie and is used to dilate the ureter at the place where a stone has become lodged or to dilate a ureteral stricture.

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

§ 876.5520 Urethral dilator.

(a) *Identification.* A urethral dilator is a device that consists of a slender hollow or solid instrument made of metal, plastic, or other suitable material in a cylindrical form and in a range of sizes and flexibilities. The device may include a mechanism to expand the portion of the device in the urethra and indicate the degree of expansion on a dial. It is used to dilate the urethra. This generic type of device includes the mechanical urethral dilator, urological bougies, metal or plastic urethral sound, urethrometer, filiform, and filiform follower.

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

(2) Class I for the urethrometer, urological bougie, filiform and filiform follower, and metal or plastic urethral sound. The 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 § 876.9.

[48 FR 53023, Nov. 23, 1983, as amended at 61 FR 1122, Jan. 16, 1996; 66 FR 38802, July 25, 2001]

§ 876.5540 Blood access device and accessories.

(a) *Identification.* A blood access device and accessories is a device intended to provide access to a patient's blood for hemodialysis or other chronic uses. When used in hemodialysis, it is part of an artificial kidney system for the treatment of patients with renal failure or toxemic conditions and provides access to a patient's blood for hemodialysis. The device includes implanted blood access devices, nonimplanted blood access devices, and accessories for both the implanted and nonimplanted blood access devices.

(1) The implanted blood access device consists of various flexible or rigid