§ 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 occlude 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, 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 mechanical/hydraulic urinary continence device shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.


§ 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 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
§ 876.5540 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 this chapter subject to the limitations in §876.9.

§ 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 tubes, which are surgically implanted in appropriate blood vessels, may come through the skin, and are intended to remain in the body for 30 days or more. This generic type of device includes various shunts and connectors specifically designed to provide access to blood, such as the arteriovenous (A-V) shunt cannula and vessel tip.

(2) The nonimplanted blood access device consists of various flexible or rigid tubes, such as catheters, cannulae or hollow needles, which are inserted into appropriate blood vessels or a vascular graft prosthesis (§§870.3450 and 870.3460), and are intended to remain in the body for less than 30 days. This generic type of device includes fistula needles, the single needle dialysis set (coaxial flow needle), and the single needle dialysis set (alternating flow needle).

(3) Accessories common to either type include the shunt adaptor, cannula clamp, shunt connector, shunt stabilizer, vessel dilator, disconnect forceps, shunt guard, crimp plier, tube plier, crimp ring, joint ring, fistula adaptor, and declotting tray (including contents).

(b) Classification. (1) Class III (premarket approval) for the implanted blood access device.