Subpart C—Monitoring Devices

§ 876.2040 Enuresis alarm.
(a) Identification. An enuresis alarm is a device intended for use in treatment of bedwetting. Through an electrical trigger mechanism, the device sounds an alarm when a small quantity of urine is detected on a sensing pad. This generic type of device includes conditioned response enuresis alarms.
(b) Classification. Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 876.9.

Subpart D—Prosthetic Devices

§ 876.3350 Penile inflatable implant.
(a) Identification. A penile inflatable implant is a device that consists of two inflatable cylinders implanted in the penis, connected to a reservoir filled with radiopaque fluid implanted in the abdomen, and a subcutaneous manual pump implanted in the scrotum. When the cylinders are inflated, they provide rigidity to the penis. This device is used in the treatment of erectile impotence.
(b) Classification. Class III (premarket approval).
(c) Date premarket approval application (PMA) or notice of completion of a product development protocol (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 July 5, 1995, for any penile inflatable implant that was in commercial distribution before May 28, 1976, or that has on or before July 5, 1995, been found to be substantially equivalent to a penile inflatable prosthesis that was in commercial distribution before May 28, 1976. Any other penile inflatable implant shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

Subpart E—Surgical Devices

§ 876.4020 Fiberoptic light ureteral catheter.
(a) Identification. A fiberoptic light ureteral catheter is a device that consists of a fiberoptic bundle that emits light throughout its length and is...
shaped so that it can be inserted into the ureter to enable the path of the ureter to be seen during lower abdominal or pelvic surgery.

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

§ 876.4270 Colostomy rod.
(a) Identification. A colostomy rod is a device used during the loop colostomy procedure. A loop of colon is surgically brought out through the abdominal wall and the stiff colostomy rod is placed through the loop temporarily to keep the colon from slipping back through the surgical opening.
(b) Classification. Class II (performance standards).

§ 876.4300 Endoscopic electrosurgical unit and accessories.
(a) Identification. An endoscopic electrosurgical unit and accessories is a device used to perform electrosurgical procedures through an endoscope. This generic type of device includes the electrosurgical generator, patient plate, electric biopsy forceps, electrode, flexible snare, electrosurgical alarm system, electrosurgical power supply unit, electrical clamp, self-opening rigid snare, flexible suction coagulator electrode, patient return wristlet, contact jelly, adaptor to the cord for transurethral surgical instruments, the electric cord for transurethral surgical instruments, and the transurethral desiccator.
(b) Classification. Class II (performance standards).

§ 876.4480 Electrohydraulic lithotriptor.
(a) Identification. An electrohydraulic lithotriptor is an AC-powered device used to fragment urinary bladder stones. It consists of a high voltage source connected by a cable to a bipolar electrode that is introduced into the urinary bladder through a cystoscope. The electrode is held against the stone in a water-filled bladder and repeated electrical discharges between the two poles of the electrode cause electrohydraulic shock waves which disintegrate the stone.
(b) Classification. Class II. The special control for this device is FDA’s “Guidance for the Content of Premarket Notifications for Intracorporeal Lithotripters.”

§ 876.4530 Gastroenterology-urology fiberoptic retractor.
(a) Identification. A gastroenterology-urology fiberoptic retractor is a device used to remove debris and fluids during gastroenterological and urological procedures by drainage, aspiration, or irrigation. This generic type of device includes the fluid evacuator system, manually powered bladder evacuator, and the AC-powered vacuum pump.
(b) Classification. (i) Class II (special controls) for the gastroenterology-urology evacuator when other than manually powered. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to §876.9.

(2) Class I for the gastroenterology-urology evacuator when manually powered. The device subject to this paragraph (b)(2) is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.


§ 876.4400 Hemorrhoidal ligator.
(a) Identification. A hemorrhoidal ligator is a device used to cut off the blood flow to hemorrhoidal tissue by means of a ligature or band placed around the hemorrhoid.
(b) Classification. Class II (performance standards).

§ 876.4450 Mechanical lithotriptor.
(a) Identification. A mechanical lithotriptor is a device with steel jaws that is inserted into the urinary bladder to grasp and crush bladder stones.
(b) Classification. Class II (performance standards).

§ 876.4530 Gastroenterology-urology fiberoptic retractor.
(a) Identification. A gastroenterology-urology fiberoptic retractor is a device that consists of a mechanical retractor with a fiberoptic light system that is used to illuminate deep surgical sites.