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 prosthesis 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).