Subpart F—Therapeutic Devices

§ 876.5010 Biliary catheter and accessories.

(a) Identification. A biliary catheter and accessories is a tubular flexible device used for temporary or prolonged drainage of the biliary tract, for splinting of the bile duct during healing, or for preventing stricture of the bile duct. This generic type of device may include a bile collecting bag that is attached to the biliary catheter by a connector and fastened to the patient with a strap.

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

§ 876.5020 External penile rigidity devices.

(a) Identification. External penile rigidity devices are devices intended to create or maintain sufficient penile rigidity for sexual intercourse. External penile rigidity devices include vacuum pumps, constriction rings, and penile splints which are mechanical, powered, or pneumatic devices.

(b) Classification. Class II (special controls). The devices are exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in §876.9. The special control for these devices is the FDA guidance document entitled “Class II Special Controls Guidance Document: External Penile Rigidity Devices.” See §876.1(e) for the availability of this guidance document.

[69 FR 77623, Dec. 28, 2004]

§ 876.5030 Continent ileostomy catheter.

(a) Identification. A continent ileostomy catheter is a flexible tubular device used as a form during surgery for continent ileostomy and it provides drainage after surgery. Additionally, the device may be inserted periodically by the patient for routine care to empty the ileal pouch. This generic type of device includes the rectal catheter for continent ileostomy.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in...