

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 54 FR 25049, June 12, 1989; 66 FR 38801, July 25, 2001]

§ 876.4770 Urethrotome.

(a) *Identification.* A urethrotome is a device that is inserted into the urethra and used to cut urethral strictures and enlarge the urethra. It is a metal instrument equipped with a dorsal-fin cutting blade which can be elevated from its sheath. Some urethrotomes incorporate an optical channel for visual control.

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

§ 876.4890 Urological table and accessories.

(a) *Identification.* A urological table and accessories is a device that consists of a table, stirrups, and belts used to support a patient in a suitable position for endoscopic procedures of the lower urinary tract. The table can be adjusted into position manually or electrically.

(b) *Classification.* (1) Class II (special controls) for the electrically powered urological table and accessories. 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 manually powered table and accessories, and for stirrups for electrically powered table. The device subject to this paragraph (b)(2) 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; 63 FR 59228, Nov. 3, 1998; 66 FR 38801, July 25, 2001]

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 heal-

ing, 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 subpart E of part 807 of this chapter subject to the limitations in § 876.9.

[48 FR 53023, Nov. 23, 1983, as amended at 54 FR 25050, June 12, 1989; 66 FR 38801, July 25, 2001]

§ 876.5090 Suprapubic urological catheter and accessories.

(a) *Identification.* A suprapubic urological catheter and accessories is a flexible tubular device that is inserted through the abdominal wall into the

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urinary bladder with the aid of a trocar and cannula. The device is used to pass fluids to and from the urinary tract. This generic type of device includes the suprapubic catheter and tube, Malecot catheter, catheter punch instrument, suprapubic drainage tube, and the suprapubic cannula and trocar.

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

(2) Class I for the catheter punch instrument, nondisposable cannula and trocar, and gastro-urological trocar. 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 38801, July 25, 2001]

§ 876.5130 Urological catheter and accessories.

(a) *Identification*. A urological catheter and accessories is a flexible tubular device that is inserted through the urethra and used to pass fluids to or from the urinary tract. This generic type of device includes radiopaque urological catheters, ureteral catheters, urethral catheters, coudé catheters, balloon retention type catheters, straight catheters, upper urinary tract catheters, double lumen female urethrographic catheters, disposable ureteral catheters, male urethrographic catheters, and urological catheter accessories including ureteral catheter stylets, ureteral catheter adapters, ureteral catheter holders, ureteral catheter stylets, ureteral catheterization trays, and the gastro-urological irrigation tray (for urological use).

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

(2) Class I for the ureteral stylet (guidewire), stylet for gastrourological catheter, ureteral catheter adapter, ureteral catheter connector, and ureteral catheter holder. The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of

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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 38801, July 25, 2001]

§ 876.5160 Urological clamp for males.

(a) *Identification*. A urological clamp for males is a device used to close the urethra of a male to control urinary incontinence or to hold anesthetic or radiography contrast media in the urethra temporarily. It is an external clamp.

(b) *Classification*. Class I (general controls). Except when intended for internal use or use on females, the device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 876.9.

[48 FR 53023, Nov. 23, 1983, as amended at 65 FR 2317, Jan. 14, 2000]

§ 876.5210 Enema kit.

(a) *Identification*. An enema kit is a device intended to instill water or other fluids into the colon through a nozzle inserted into the rectum to promote evacuation of the contents of the lower colon. The device consists of a container for fluid connected to the nozzle either directly or via tubing. This device does not include the colonic irrigation system (§ 876.5220).

(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 § 876.9. The device is exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of § 820.180 of this chapter, with respect to general requirements concerning records, and § 820.198 of this chapter, with respect to complaint files.

[48 FR 53023, Nov. 23, 1983, as amended at 65 FR 2317, Jan. 14, 2000]

§ 876.5220 Colonic irrigation system.

(a) *Identification*. A colonic irrigation system is a device intended to instill water into the colon through a nozzle inserted into the rectum to cleanse (evacuate) the contents of the lower colon. The system is designed to allow evacuation of the contents of the colon