§ 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 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.


§ 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 urothorographic catheters, disposable ureteral catheters, male urothorographic catheters, and urological catheter accessories including ureteral catheter styles, ureteral catheter adapters, ureteral catheter holders, ureteral catheter styles, 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 this chapter subject to the limitations in §876.9.


§ 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.


§ 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.