§ 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 the limitations in §876.9. The special control for these devices is the FDA guidance document entitled "Class II Special Controls Guidance Document: Urological Table and Accessories." See §876.1(e) for the availability of this guidance document.

[69 FR 77623, Dec. 28, 2004]

§ 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 (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: Urological Table and Accessories." See §876.1(e) for the availability of this guidance document.

[69 FR 77623, Dec. 28, 2004]