§ 876.4590 Interlocking urethral sound.

(a) Identification. An interlocking urethral sound is a device that consists of two metal sounds (elongated instruments for exploring or sounding body cavities) with interlocking ends, such as with male and female threads or a rounded point and mating socket, used in the repair of a ruptured urethra. The device may include a protective cap to fit over the metal threads.

(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.

§ 876.4620 Ureteral stent.

(a) Identification. A ureteral stent is a tube-like implanted device that is inserted into the ureter to provide ureteral rigidity and allow the passage of urine. The device may have finger-like protrusions or hooked ends to keep the tube in place. It is used in the treatment of ureteral injuries and ureteral obstruction.

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

§ 876.4650 Water jet renal stone dislodger system.

(a) Identification. A water jet renal stone dislodger system is a device used to dislodge stones from renal calyces (recesses of the pelvis of the kidney) by means of a pressurized stream of water through a conduit. The device is used in the surgical removal of kidney stones.

(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.

§ 876.4680 Ureteral stone dislodger.

(a) Identification. A ureteral stone dislodger is a device that consists of a bougie or a catheter with an expandable wire basket near the tip, a special flexible tip, or other special construction. It is inserted through a cystoscope and used to entrap and remove stones from the ureter. This generic type of device includes the metal basket and the flexible ureteral stone dislodger.

(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.

§ 876.4730 Manual gastroenterology-urology surgical instrument and accessories.

(a) Identification. A manual gastroenterology-urology surgical instrument and accessories is a device designed to be used for gastroenterological and urological surgical procedures. The device may be nonpowered, hand-held, or hand-manipulated. Manual gastroenterology-urology surgical instruments include the biopsy forceps cover, biopsy tray without biopsy instruments, line clamp, nonpowered rectal probe, nonelectrical clamp, colostomy spur-crushers, locking device for intestinal clamp, needle holder, gastro-urology hook, gastro-urology probe and director, nonself-retaining retractor, laparotomy rings, nonelectrical snare, rectal specula, bladder neck spreader, self-retaining retractor, and scoop.

(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.

§ 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).