used to dilate a stricture of the esophagus. This generic type of device includes esophageal or gastrointestinal bougies and the esophageal dilator (metal olive).

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

§ 876.5450 Rectal dilator.

(a) Identification. A rectal dilator is a device designed to dilate the anal sphincter and canal when the size of the anal opening may interfere with its function or the passage of an examining instrument.

(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.

§ 876.5470 Ureteral dilator.

(a) Identification. A ureteral dilator is a device that consists of a specially shaped catheter or bougie and is used to dilate the ureter at the place where a stone has become lodged or to dilate a ureteral stricture.

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

§ 876.5520 Urethral dilator.

(a) Identification. A urethral dilator is a device that consists of a slender hollow or solid instrument made of metal, plastic, or other suitable material in a cylindrical form and in a range of sizes and flexibilities. The device may include a mechanism to expand the portion of the device in the urethra and indicate the degree of expansion on a dial. It is used to dilate the urethra. This generic type of device includes the mechanical urethral dilator, urological bougies, metal or plastic urethral sound, urethrometer, filliform, and filiform follower.

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

(2) Class I for the urethrometer, urological bougie, filliform and filiform follower, and metal or plastic urethral sound. 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.

§ 876.5540 Blood access device and accessories.

(a) Identification. A blood access device and accessories is a device intended to provide access to a patient’s blood for hemodialysis or other chronic uses. When used in hemodialysis, it is part of an artificial kidney system for the treatment of patients with renal failure or toxemic conditions and provides access to a patient’s blood for hemodialysis. The device includes implanted blood access devices, nonimplanted blood access devices, and accessories for both the implanted and nonimplanted blood access devices.

(1) The implanted blood access device consists of various flexible or rigid tubes, which are surgically implanted in appropriate blood vessels, may come through the skin, and are intended to remain in the body for 30 days or more. This generic type of device includes various shunts and connectors specifically designed to provide access to blood, such as the arteriovenous (A-V) shunt cannula and vessel tip.

(2) The nonimplanted blood access device consists of various flexible or rigid tubes, such as catheters, cannulae or hollow needles, which are inserted into appropriate blood vessels or a vascular graft prosthesis (§§870.3450 and 870.3460), and are intended to remain in the body for less than 30 days. This generic type of device includes fistula needles, the single needle dialysis set (coaxial flow needle), and the single needle dialysis set (alternating flow needle).

(3) Accessories common to either type include the shunt adaptor, cannula clamp, shunt connector, shunt stabilizer, vessel dilator, disconnect forceps, shunt guard, crimp plier, tube plier, crimp ring, joint ring, fistula adaptor, and declotting tray (including contents).

(b) Classification. (1) Class III (premarket approval) for the implanted blood access device.
§ 876.5600 Sorbent regenerated dialysate delivery system for hemodialysis.

(a) Identification. A sorbent regenerated dialysate delivery system for hemodialysis is a device that is part of an artificial kidney system for the treatment of patients with renal failure or toxemic conditions, and that consists of a sorbent cartridge and the means to circulate dialysate through this cartridge and the dialysate compartment of the dialyzer. The device is used with the extracorporeal blood system and the dialyzer of the hemodialysis system and accessories (§876.5820). The device includes the means to maintain the temperature, conductivity, electrolyte balance, flow rate and pressure of the dialysate, and alarms to indicate abnormal dialysate conditions. The sorbent cartridge may include absorbent, ion exchange and catalytic materials.

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

§ 876.5630 Peritoneal dialysis system and accessories.

(a) Identification. (1) A peritoneal dialysis system and accessories is a device that is used as an artificial kidney system for the treatment of patients with renal failure or toxemic conditions, and that consists of a peritoneal access device, an administration set for peritoneal dialysis, a source of dialysate, and, in some cases, a water purification mechanism. After the dialysate is instilled into the patient’s peritoneal cavity, it is allowed to dwell there so that undesirable substances from the patient’s blood pass through the lining membrane of the peritoneal cavity into this dialysate. These substances are then removed when the dialysate is drained from the patient. The peritoneal dialysis system may regulate and monitor the dialysate temperature, volume, and delivery rate together with the time course of each cycle of filling, dwell time, and draining of the peritoneal cavity or manual controls may be used. This generic device includes the semiautomatic and the automatic peritoneal delivery system.

(2) The peritoneal access device is a flexible tube that is implanted through the abdominal wall into the peritoneal cavity and that may have attached cuffs to provide anchoring and a skin seal. The device is either a single use peritoneal catheter, intended to remain in the peritoneal cavity for less than 30 days, or a long term peritoneal catheter. Accessories include stylets and trocars to aid in the insertion of the catheter and an obturator to maintain the patency of the surgical fistula in the abdominal wall between treatments.

(3) The disposable administration set for peritoneal dialysis consists of tubing, an optional reservoir bag, and appropriate connectors. It may include a peritoneal dialysate filter to trap and remove contaminating particles.

(4) The source of dialysate may be sterile prepackaged dialysate (for semiautomatic peritoneal dialysate delivery systems or “cycler systems”) or dialysate prepared from dialysate concentrate and sterile purified water (for automatic peritoneal dialysate delivery systems or “reverse osmosis” systems). Prepackaged dialysate intended for use with either of the peritoneal dialysate delivery systems is regulated by FDA as a drug.