§ 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 healing, 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).

§ 876.5030  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 (performance standards).

§ 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 rectal catheter for continent ileostomy.

(b) Classification. Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807 of this chapter.

§ 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 urethrocatheters, disposable ureteral catheters, male urethrocatheters, 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 gastro-urological 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.

§ 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 radiographic contrast media in the urethra temporarily. It is an external clamp.

(b) Classification. Class I (general controls).

§ 876.5210  Enema kit.

(a) Identification. An enema kit is a device intended to instil water or other fluids into the colon through a nozzle inserted into the rectum to pro-
mote 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 current good manufacturing practice regulations in Part 820, with the exception of §820.180, with respect to general requirements concerning records, and §820.198, with respect to complaint files.

§ 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 during the administration of the colonic irrigation. The device consists of a container for fluid connected to the nozzle via tubing and includes a system which enables the pressure, temperature, or flow of water through the nozzle to be controlled. The device may include a console-type toilet and necessary fittings to allow the device to be connected to water and sewer pipes. The device may use electrical power to heat the water. The device does not include the enema kit (§876.5210).

(b) Classification.
(1) Class II (performance standards) when the device is intended for colon cleansing when medically indicated, such as before radiological or endoscopic examinations.
(2) Class III (premarket approval) when the device is intended for other uses, including colon cleansing routinely for general well being.

(c) Date PMA or notice of completion of a PDP is required.

No effective date has been established of the requirement for premarket approval for the device intended for the uses described in paragraph (b)(2). See §876.3.


§ 876.5250 Urine collector and accessories.

(a) Identification. A urine collector and accessories is a device intended to collect urine. The device and accessories consist of tubing, a suitable receptacle, connectors, mechanical supports, and may include a means to prevent the backflow of urine or ascent of infection. The two kinds of urine collectors are: (1) A urine collector and accessories intended to be connected to an indwelling catheter, which includes the urinary drainage collection kit and the closed urine drainage system and drainage bag; and (2) a urine collector and accessories not intended to be connected to an indwelling catheter, which includes the corrugated rubber sheath, pediatric urine collector, leg bag for external use, urosheath type incontinence device, and the paste-on device for incontinence.

(b) Classification.
(1) Class II (performance standards) for a urine collector and accessories intended to be connected to an indwelling catheter.
(2) Class I (general controls) for a urine collector and accessories not intended to be connected to an indwelling catheter. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice regulations in Part 820, with the exception of §820.180, with respect to general requirements concerning records, and §820.198, with respect to complaint files.

§ 876.5270 Implanted electrical urinary continence device.

(a) Identification. An implanted electrical urinary device is a device intended for treatment of urinary incontinence that consists of a receiver implanted in the abdomen with electrodes for pulsed-stimulation that are implanted either in the bladder wall or in the pelvic floor, and a battery-powered transmitter outside the body.

(b) Classification. Class III (premarket approval).

(c) Date PMA or notice of completion of a PDP is required. No effective date has been established of the requirement for premarket approval. See §876.3.


§ 876.5280 Implanted mechanical/hydraulic urinary continence device.

(a) Identification. An implanted mechanical/hydraulic urinary continence device is a device used to treat urinary
§ 876.5320 Nonimplanted electrical continence device.

(a) Identification. A nonimplanted electrical continence device is a device that consists of a pair of electrodes on a plug or a pessary that are connected by an electrical cable to a battery-powered pulse source. The plug or pessary is inserted into the rectum or into the vagina and used to stimulate the muscles of the pelvic floor to maintain urinary or fecal continence. When necessary, the plug or pessary may be removed by the user. This device excludes an AC-powered nonimplanted electrical continence device and the powered vaginal muscle stimulator for therapeutic use (§884.5940).

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

§ 876.5365 Esophageal dilator.

(a) Identification. An esophageal dilator is a device that consists of a cylindrical instrument that may be hollow and weighted with mercury or a metal olive-shaped weight that slides on a guide, such as a string or wire and is 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 III (premarket approval).

§ 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, filiform, and filiform follower.

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

(2) Class I for the urethrometer, urological bougie, filiform 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.

§ 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, non-implanted 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.

(2) Class II (performance standards) for the nonimplanted blood access device.

(3) Class II (performance standards) for accessories for both the implanted and nonimplanted blood access devices not listed in paragraph (b)(4) of this section.

(4) Class I for the cannula clamp, disconnect forceps, crimp plier, tube plier, crimp ring, and joint ring, accessories for both the implanted and nonimplanted blood access device. The devices subject to this paragraph (b)(4) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

(c) Date PMA or notice of completion of a PDP is required. No effective date has been established of the requirement for premarket approval for the device described in paragraph (b)(1). See §876.3.


§ 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.

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

§ 876.5665 Water purification system for hemodialysis.

(a) Identification. A water purification system for hemodialysis is a device that is intended for use with a hemodialysis system and that is intended to remove organic and inorganic substances and microbial contaminants from water used to dilute dialysate concentrate to form dialysate. This generic type of device may include a water softener, sediment filter, carbon filter, and water distillation system.

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

§ 876.5820 Hemodialysis system and accessories.

(a) Identification. A hemodialysis 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 an extracorporeal blood system, a conventional dialyzer, a dialysate delivery system, and accessories. Blood from a patient flows through the tubing of the extracorporeal blood system and accessories to the blood compartment of the dialyzer, then returns through further tubing of the extracorporeal blood system to the patient. The dialyzer has two compartments that are separated by a semipermeable membrane. While the blood is in the blood compartment, undesirable substances in the blood pass through the semipermeable membrane into the dialysate in the dialysate compartment. The dialysate delivery system controls and monitors the dialysate circulating through the dialysate compartment of the dialyzer.

(1) The extracorporeal blood system and accessories consists of tubing, pumps, pressure monitors, air foam or bubble detectors, and alarms to keep blood moving safely from the blood access device and accessories for hemodialysis (§876.5540) to the blood compartment of the dialyzer and back to the patient.

(2) The conventional dialyzer allows a transfer of water and solutes between the blood and the dialysate through the semipermeable membrane. The semipermeable membrane of the conventional dialyzer has a sufficiently low permeability to water that an ultrafiltration controller is not required to prevent excessive loss of water from the patient's blood. The conventional dialyzer does not include hemodialyzers with the disposable inserts (Kii1 type) (§876.5930) or dialyzers of high permeability (§876.5960).

(3) The dialysate delivery system consists of mechanisms that monitor and control the temperature, conductivity, flow rate, and pressure of the dialysate.
the dialysate and circulates dialysate through the dialysate compartment of the dialyzer. The dialysate delivery system includes the dialysate concentrate for hemodialysis (liquid or powder) and alarms to indicate abnormal dialysate conditions. This dialysate delivery system does not include the sorbent regenerated dialysate delivery system for hemodialysis (§876.5600), the dialysate delivery system of the peritoneal dialysis system and accessories (§876.5630), or the controlled dialysate delivery system of the high permeability hemodialysis system (§876.5860).

(4) Remote accessories to the hemodialysis system include the unpowered dialysis chair without a scale, the powered dialysis chair without a scale, the dialyzer holder set, dialysis tie gun and ties, and hemodialysis start/stop tray.

(b) Classification.

(1) Class II (performance standards) for hemodialysis systems and all accessories directly associated with the extracorporeal blood system and the dialysate delivery system.

(2) Class I for other accessories of the hemodialysis system remote from the extracorporeal blood system and the dialysate delivery system. These devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in Subpart E of Part 807 of this chapter.

§ 876.5830 Hemodialyzer with disposable insert (Kiil type).

(a) Identification. A hemodialyzer with disposable inserts (Kiil type) is a device that is used as a part of an artificial kidney system for the treatment of patients with renal failure or toxemic conditions and that includes disposable inserts consisting of layers of semipermeable membranes which are sandwiched between support plates. The device is used with the extracorporeal blood system and the dialysate delivery system of the hemodialysis system and accessories (§876.5820).

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

§ 876.5860 High permeability hemodialysis system.

(a) Identification. A high permeability hemodialysis system is a device that is used as an artificial kidney system for the treatment of patients with renal failure or toxemic conditions, and that has a dialyzer with a semipermeable membrane that is more permeable to water than the semipermeable membrane of the conventional dialyzer. The device system consists of an extracorporeal blood system, a high permeability dialyzer, and a controlled dialysate delivery system that incorporates an ultrafiltration controller to prevent excessive loss of water from the patient’s blood. This highly permeable, semipermeable membrane may also permit greater loss of higher molecular weight substances from the blood, compared with the conventional dialyzer of the hemodialysis system and accessories (§876.5820). The extracorporeal blood system is the same generic type of extracorporeal blood system that is used in the hemodialysis system and accessories (§876.5820). The controlled dialysate delivery system also is similar to the conventional dialysate delivery system of the hemodialysis system and accessories (§876.5820), with the addition of an ultrafiltration controller to regulate the rate of the removal of water from the patient’s blood and ensure that the pressure on the dialysate side of the membrane is always lower than on the blood side. This generic type of device includes the sealed dialysate delivery system.

(b) Classification. Class III (premarket approval).

(c) Date PMA or notice of completion of a PDP is required. No effective date has been established of the requirement for premarket approval. See §876.3.

§ 876.5870 Sorbent hemoperfusion system.

(a) Identification. A sorbent hemoperfusion system is a device that
§ 876.5880 Isolated kidney perfusion and transport system and accessories.

(a) Identification. An isolated kidney perfusion and transport system and accessories is a device that is used to support a donated or a cadaver kidney and to maintain the organ in a near-normal physiologic state until it is transplanted into a recipient patient. This generic type of device may include tubing, catheters, connectors, an ice storage or freezing container with or without bag or preservatives, pulsatile or nonpulsatile hypothermic isolated organ perfusion apparatus with or without oxygenator, and disposable perfusion set.

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

§ 876.5895 Ostomy irrigator.

(a) Identification. An ostomy irrigator is a device that consists of a container for fluid, tubing with a cone-shaped tip or a soft and flexible catheter with a retention shield and that is used to wash out the colon through a colostomy, a surgically created opening of the colon on the surface of the body.

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

§ 876.5900 Ostomy pouch and accessories.

(a) Identification. An ostomy pouch and accessories is a device that consists of a bag that is attached to the patient's skin by an adhesive material and that is intended for use as a receptacle for collection of fecal material or urine following an ileostomy, colostomy, or ureterostomy (a surgically created opening of the small intestine, large intestine, or the ureter on the surface of the body). This generic type of device and its accessories includes the ostomy pouch, ostomy adhesive, the disposable colostomy appliance, ostomy collector, colostomy pouch, urinary ileostomy bag, urine collecting ureterostomy bag, ostomy drainage bag with adhesive, stomal bag, ostomy protector, and the ostomy size selector, but excludes ostomy pouches which incorporate arsenic-containing compounds.

(b) Classification. Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807 of this chapter.

§ 876.5920 Protective garment for incontinence.

(a) Identification. A protective garment for incontinence is a device that consists of absorbent padding and a fluid barrier and that is intended to protect an incontinent patient's garment from the patient's excreta. This generic type of device does not include diapers for infants.

(b) Classification. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of §820.190, regarding general requirements concerning records, and §820.198, regarding complaint files.

§ 876.5955 Peritoneovenous shunt.

(a) Identification. A peritoneovenous shunt is an implanted device that consists of a catheter and a pressure acti-
vated one-way valve. The catheter is implanted with one end in the peritoneal cavity and the other in a large vein. This device enables ascitic fluid in the peritoneal cavity to flow into the venous system for the treatment of intractable ascites.

(b) Classification. Class III (premarket approval).

(c) Date PMA or notice of completion of a PDP is required. No effective date has been established of the requirement for premarket approval. See §876.3.


§ 876.5970 Hernia support.

(a) Identification. A hernia support is a device, usually made of elastic, canvas, leather, or metal, that is intended to be placed over a hernial opening (a weakness in the abdominal wall) to prevent protrusion of the abdominal contents. This generic type of device includes the umbilical truss.

(b) Classification. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter. The device is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of §820.180, regarding general requirements concerning records, and §820.198, regarding complaint files.


§ 876.5980 Gastrointestinal tube and accessories.

(a) Identification. A gastrointestinal tube and accessories is a device that consists of flexible or semi-rigid tubing used for instilling fluids into, withdrawing fluids from, splinting, or suppressing bleeding of the alimentary tract. This device may incorporate an integral inflatable balloon for retention or hemostasis. This generic type of device includes the hemostatic bag, irrigation and aspiration catheter (gastric, colonic, etc.), rectal catheter, sterile infant gavage set, gastrointestinal string and tubes to locate internal bleeding, double lumen tube for intestinal decompression or intubation, feeding tube, gastroenterostomy tube, Levine tube, nasogastric tube, single lumen tube with mercury weight balloon for intestinal intubation or decompression, and gastro-urological irrigation tray (for gastrological use).

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

(2) Class I (general controls) for the dissolvable nasogastric feed tube guide for the nasogastric tube.

[49 FR 573, Jan. 5, 1984]