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 gastrointestinal use).

(b) Classification. (1) Class II (special controls). The barium enema retention catheter and tip with or without a bag that is a gastrointestinal tube and accessory is exempt from the premarket notification procedures in subpart E of this part subject to the limitations in §876.9.

(2) Class I (general controls) for the dissolvable nasogastric feed tube guide for the nasogastric tube. The class I device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to §876.9.


§876.5990 Extracorporeal shock wave lithotripter.

(a) Identification. An extracorporeal shock wave lithotripter is a device that focuses ultrasonic shock waves into the body to noninvasively fragment urinary calculi within the kidney or ureter. The primary components of the device are a shock wave generator, high voltage generator, control console, imaging/localization system, and patient table. Prior to treatment, the urinary stone is targeted using either an integral or stand-alone localization/imaging system. Shock waves are typically generated using electrostatic spark discharge (spark gap), electromagnetically repelled membranes, or piezoelectric crystal arrays, and focused onto the stone with either a specially designed reflector, dish, or acoustic lens. The shock waves are created under water within the shock wave generator, and are transferred to the patient’s body using an appropriate acoustic interface. After the stone has been fragmented by the focused shock waves, the fragments pass out of the body with the patient’s urine.

(b) Classification. Class II (special controls) (FDA guidance document: “Guidance for the Content of Premarket Notifications (510(k)s) for Extracorporeal Shock Wave Lithotripters Indicated for the Fragmentation of Kidney and Ureteral Calculi.”)

[65 FR 48612, Aug. 9, 2000]
§ 878.1 21 CFR Ch. I (4–1–16 Edition)

878.4014 Nonresorbable gauze/sponge for external use.
878.4015 Wound dressing with poly (diallyl dimethyl ammonium chloride) (pDADMAC) additive.
878.4018 Hydrophilic wound dressing.
878.4020 Occlusive wound dressing.
878.4022 Hydrogel wound dressing and burn dressing.
878.4025 Silicone sheeting.
878.4040 Surgical apparel.
878.4100 Organ bag.
878.4120 Surgical camera and accessories.
878.4200 Introduction/drainage catheter and accessories.
878.4300 Implantable clip.
878.4320 Removable skin clip.
878.4340 Contact cooling system for aesthetic use.
878.4350 Cryosurgical unit and accessories.
878.4360 Scalp cooling system to reduce the likelihood of chemotherapy-induced alopecia.
878.4370 Surgical drape and drape accessories.
878.4380 Drape adhesive.
878.4400 Electrosurgical cutting and coagulation device and accessories.
878.4410 Low energy ultrasound wound cleaner.
878.4413 Absorbable staple.
878.4420 Nonabsorbable gauze for internal use.
878.4442 Nonabsorbable expandable hemostatic sponge for temporary internal use.
878.4460 Surgeon’s glove.
878.4470 Surgeon’s gloving cream.
878.4480 Absorbable powder for lubricating a surgeon’s glove.
878.4490 Absorbable hemostatic agent and dressing.
878.4493 Absorbable polyglycolic-acid (surgical sutures).
878.4494 Absorbable poly(hydroxybutyrate) surgical suture produced by recombinant DNA technology.
878.4495 Stainless steel suture.
878.4500 Polytetrafluoroethylene injectable.
878.4520 Surgical lamp.
878.4530 Focused ultrasound stimulator system for aesthetic use.
878.4540 Ultraviolet lamp for dermatologic disorders.
878.4550 Sunlamp products and ultraviolet lamps intended for use in sunlamp products.
878.4560 Skin marker.
878.4570 Internal tissue marker.
878.4600 Non-Powered suction apparatus.
878.4630 Surgical skin degreaser or adhesive tape solvent.
878.4750 Implantable staple.
878.4755 Absorbable lung biopsy plug.
878.4756 Removable skin staple.
878.4780 Powered suction pump.
878.4781 Powered suction apparatus.
878.4790 Powered surgical instrument for improvement in the appearance of cellulite.
878.4810 Manual surgical instrument for general use.
878.4815 Laser surgical instrument for use in general and plastic surgery and in dermatology.
878.4820 Surgical instrument motors and accessories.
878.4830 Absorbable surgical gut suture.
878.4840 Absorbable polydioxanone surgical suture.
878.4890 Manual operating table and accessories and manual operating chair and accessories.
878.4990 Operating tables and accessories and operating chairs and accessories.
878.5000 Nonabsorbable polyethylene terephthalate) surgical suture.
878.5010 Nonabsorbable polypropylene surgical suture.
878.5020 Nonabsorbable polyamide surgical suture.
878.5030 Natural nonabsorbable silk surgical suture.
878.5035 Nonabsorbable expanded polytetrafluoroethylene surgical suture.
878.5040 Suction lipoplasty system.

Subpart F—Therapeutic Devices

878.5070 Air-handling apparatus for a surgical operating room.
878.5350 Needle-type epilator.
878.5360 Tweezer-type epilator.
878.5400 Low level laser system for aesthetic use.
878.5560 Topical oxygen chamber for extremities.
878.5900 Nonpneumatic tourniquet.
878.5910 Pneumatic tourniquet.


S O U R C E : 53 FR 23872, June 24, 1988, unless otherwise noted.


Subpart A—General Provisions

§ 878.1 Scope.

(a) This part sets forth the classification of general and plastic surgery devices intended for human use that are in commercial distribution.
(b) The identification of a device in a regulation in this part is not a precise description of every device that is, or