

part 807 of this chapter subject to §876.9.

[49 FR 573, Jan. 5, 1984, as amended at 65 FR 2317, Jan. 14, 2000; 65 FR 76932, Dec. 8, 2000]

§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 Pre-market Notifications (510(k)'s) for Extracorporeal Shock Wave Lithotripters Indicated for the Fragmentation of Kidney and Ureteral Calculi.")

[65 FR 48612, Aug. 9, 2000]

PART 878—GENERAL AND PLASTIC SURGERY DEVICES

Subpart A—General Provisions

Sec.

878.1 Scope.

878.3 Effective dates of requirement for pre-market approval.

878.9 Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).

Subpart B—Diagnostic Devices

878.1800 Speculum and accessories.

Subpart C [Reserved]

Subpart D—Prosthetic Devices

878.3250 External facial fracture fixation appliance.
 878.3300 Surgical mesh.
 878.3500 Polytetrafluoroethylene with carbon fibers composite implant material.
 878.3530 Silicone inflatable breast prosthesis.
 878.3540 Silicone gel-filled breast prosthesis.
 878.3550 Chin prosthesis.
 878.3590 Ear prosthesis.
 878.3610 Esophageal prosthesis.
 878.3680 Nose prosthesis.
 878.3720 Tracheal prosthesis.
 878.3750 External prosthesis adhesive.
 878.3800 External aesthetic restoration prosthesis.
 878.3900 Inflatable extremity splint.
 878.3910 Noninflatable extremity splint.
 878.3925 Plastic surgery kit and accessories.

Subpart E—Surgical Devices

878.4010 Tissue adhesive.
 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.
 878.4160 Surgical camera and accessories.
 878.4200 Introduction/drainage catheter and accessories.
 878.4300 Implantable clip.
 878.4320 Removable skin clip.
 878.4350 Cryosurgical unit and accessories.
 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.
 878.4440 Eye pad.
 878.4450 Nonabsorbable gauze for 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 poly(glycolide/L-lactide) surgical suture.
 878.4494 Absorbable poly(hydroxybutyrate) surgical suture produced by recombinant DNA technology.
 878.4495 Stainless steel suture.