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]

PART 878—GENERAL AND PLASTIC SURGERY DEVICES

Subpart A—General Provisions

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878.1800 Speculum and accessories.

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878.3250 External facial fracture fixation appliance.
878.3300 Surgical mesh.
878.3500 Polytetrafluoroethylene with carbon fibers composite implant material.
878.3520 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.
878.4011 Tissue adhesive with adjunct wound closure device for topical approximation of skin.
878.4014 Nonresorbable gauze/sponge for external use.
878.4015 Wound dressing with poly (dialyl 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.
878.4150 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.
878.4370 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/1-lactide) surgical suture.
878.4494 Absorbable poly(hydroxybutyrate) surgical suture produced by recombinant DNA technology.
878.4495 Stainless steel suture.
878.4500 Polytetrafluoroethylene injectable.
878.4580 Surgical lamp.
878.4590 Focused ultrasound stimulator system for aesthetic use.
878.4630 Ultraviolet lamp for dermatologic disorders.
878.4635 Ultraviolet lamp for tanning.
878.4660 Skin marker.
878.4680 Nonpowered, single patient, portable suction apparatus.
878.4683 Non-Powered suction apparatus device intended for negative pressure wound therapy.
878.4700 Surgical microscope and accessories.
878.4730 Surgical skin degreaser or adhesive tape solvent.
§ 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 will be, subject to the regulation. A manufacturer who submits a premarket notification submission for a device under part 807 cannot show merely that the device is accurately described by the section title and identification provision of a regulation in this part, but shall state why the device is substantially equivalent to other devices, as required by §807.67 of this chapter.

(c) To avoid duplicative listings, a general and plastic surgery device that has two or more types of uses (e.g., used both as a diagnostic device and as a therapeutic device) is listed in one subpart only.

(d) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21 unless otherwise noted.

Subpart A—General Provisions

§ 878.1 Scope.

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878.4750 Implantable staple.
878.4760 Removable skin staple.
878.4780 Powered suction pump.
878.4800 Manual surgical instrument for general use.
878.4810 Laser surgical instrument for use in general and plastic surgery and in dermatology.
878.4820 Surgical instrument motors and accessories/attachments.
878.4830 Absorbable surgical gut suture.
878.4840 Absorbable polydioxanone surgical suture.
878.4930 Suture retention device.
878.4950 Manual operating table and accessories and manual operating chair and accessories.
878.4960 Operating tables and accessories and operating chairs and accessories.
878.5000 Nonabsorbable poly(ethylene 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.
878.5650 Topical oxygen chamber for extremities.
878.5900 Nonpneumatic tourniquet.
878.5910 Pneumatic tourniquet.


Editorial Note: Nomenclature changes to part 878 appear at 73 FR 35341, June 23, 2008.

§ 878.3 Effective dates of requirement for premarket approval.

A device included in this part that is classified into class III (premarket approval) shall not be commercially distributed after the date shown in the regulation classifying the device unless the manufacturer has an approval under section 515 of the act (unless an exemption has been granted under section 520(g)(2) of the act). An approval under section 515 of the act consists of FDA's issuance of an order approving an application for premarket approval (PMA) for the device or declaring completed a product development protocol (PDP) for the device.

(a) Before FDA requires that a device commercially distributed before the enactment date of the amendments, or a device that has been found substantially equivalent to such a device, has an approval under section 515 of the act, FDA must promulgate a regulation under section 515(b) of the act requiring such approval, except as provided in paragraphs (b) and (c) of this section. Such a regulation under section 515(b) of the act shall not be effective during the grace period ending on the 90th day after its promulgation or on the last day of the 30th full calendar year following its effective date.