

§ 878.1

21 CFR Ch. I (4-1-01 Edition)

Subpart E—Surgical Devices

- 878.4014 Nonresorbable gauze/sponge for external use.
- 878.4018 Hydrophilic wound dressing.
- 878.4020 Occlusive wound dressing.
- 878.4022 Hydrogel wound dressing and burn dressing.
- 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.
- 878.4440 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.
- 878.4495 Stainless steel suture.
- 878.4520 Polytetrafluoroethylene injectable.
- 878.4580 Surgical lamp.
- 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.
- 878.4700 Surgical microscope and accessories.
- 878.4730 Surgical skin degreaser or adhesive tape solvent.
- 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.
- 878.4930 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.
- 878.5650 Topical oxygen chamber for extremities.
- 878.5900 Nonpneumatic tourniquet.
- 878.5910 Pneumatic tourniquet.

AUTHORITY: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

SOURCE: 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 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 § 807.87 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.

§ 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