

§ 878.1

- 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.

21 CFR Ch. I (4–1–02 Edition)

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 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