

Food and Drug Administration, HHS

§ 878.3

- 878.4805 Manual percutaneous surgical set assembled in the abdomen.
- 878.4810 Laser surgical instrument for use in general and plastic surgery and in dermatology.
- 878.4815 Magnetic surgical instrument system.
- 878.4820 Surgical instrument motors and accessories/attachments.
- 878.4825 General laparoscopic power morcellation containment system.
- 878.4830 Absorbable surgical gut suture.
- 878.4840 Absorbable polydioxanone surgical suture.
- 878.4850 Blood lancets.
- 878.4860 Light based energy source device for topical application.
- 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.
- 878.4961 Mountable electromechanical surgical system for transluminal approaches.
- 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.
- 878.5050 Surgical smoke precipitator.

Subpart F—Therapeutic Devices

- 878.5070 Air-handling apparatus for a surgical operating room.
- 878.5080 Air-handling apparatus accessory.
- 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.

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

SOURCE: 53 FR 23872, June 24, 1988, unless otherwise noted.

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

Subpart A—General Provisions

§ 878.1 Scope.

(a) This part sets forth the classification of general and plastic surgery de-

vices 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.

(e) Guidance documents referenced in this part are available on the Internet at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>.

[53 FR 23872, June 24, 1988, as amended at 67 FR 77676, Dec. 19, 2002; 78 FR 18233, Mar. 26, 2013]

§ 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