

§ 878.1

- 878.4635 Sunlamp products and ultraviolet lamps intended for use in sunlamp products.
- 878.4660 Skin marker.
- 878.4670 Internal tissue marker.
- 878.4680 Nonpowered, single patient, portable suction apparatus.
- 878.4683 Non-Powered suction apparatus device intended for negative pressure wound therapy.
- 878.4685 Extracorporeal shock wave device for treatment of chronic wounds.
- 878.4700 Surgical microscope and accessories.
- 878.4730 Surgical skin degreaser or adhesive tape solvent.
- 878.4740 Surgical stapler.
- 878.4750 Implantable staple.
- 878.4755 Absorbable lung biopsy plug.
- 878.4760 Removable skin staple.
- 878.4780 Powered suction pump.
- 878.4783 Negative pressure wound therapy device for reduction of wound complications.
- 878.4790 Powered surgical instrument for improvement in the appearance of cellulite.
- 878.4800 Manual surgical instrument for general use.
- 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.
- 878.5000 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.

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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 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 pre-market 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]