

§ 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]