(b) *Classification.* Class II (special controls). Consensus standards and labeling restrictions.

[63 FR 7705, Feb. 17, 1998]

## Subpart F—Therapeutic Devices

### § 878.5070 Air-handling apparatus for a surgical operating room.

(a) *Identification.* Air-handling apparatus for a surgical operating room is a device intended to produce a directed, nonturbulent flow of air that has been filtered to remove particulate matter and microorganisms to provide an area free of contaminants to reduce the possibility of infection in the patient.

(b) *Classification.* Class II.

### § 878.5350 Needle-type epilator.

(a) *Identification.* A needle-type epilator is a device intended to destroy the dermal papilla of a hair by applying electric current at the tip of a fine needle that has been inserted close to the hair shaft, under the skin, and into the dermal papilla. The electric current may be high-frequency AC current, high-frequency AC combined with DC current, or DC current only.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 878.9.

[53 FR 23872, June 24, 1988, as amended at 61 FR 1123, Jan. 16, 1996; 66 FR 38803, July 25, 2001]

### § 878.5360 Tweezer-type epilator.

(a) *Identification.* The tweezer-type epilator is an electrical device intended to remove hair. The energy provided at the tip of the tweezer used to remove hair may be radio frequency, galvanic (direct current), or a combination of radio frequency and galvanic energy.

(b) *Classification.* Class I (general controls). The device is exempt from premarket notification procedures in subpart E of part 807 of this chapter subject to § 878.9.

[63 FR 57060, Oct. 26, 1998]

### § 878.5400 Low level laser system for aesthetic use

(a) *Identification.* A Low Level Laser System for Aesthetic Use is a device using low level laser energy for the disruption of adipocyte cells within the fat layer for the release of fat and lipids from these cells for noninvasive aesthetic use.

(b) *Classification.* Class II (special controls). The special control for this device is the FDA guidance document entitled ''Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Low Level Laser System for Aesthetic Use.'' See § 878.1(e) for the availability of this guidance document.

[76 FR 20842, Apr. 14, 2011]

### § 878.5650 Topical oxygen chamber for extremities.

(a) *Identification.* A topical oxygen chamber for extremities is a device that is intended to surround a patient's limb and apply humidified oxygen topically at a pressure slightly greater than atmospheric pressure to aid healing of chronic skin ulcers such as bedsores.

(b) *Classification.* Class II (special controls). The special control for this device is FDA's ''Class II Special Controls Guidance: Topical Oxygen Chamber for Extremities.'' See § 878.1(e) for the availability of this guidance document.

[76 FR 22807, Apr. 25, 2011]

### § 878.5900 Nonpneumatic tourniquet.

(a) *Identification.* A nonpneumatic tourniquet is a device consisting of a strap or tubing intended to be wrapped around a patient's limb and tightened to reduce circulation.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 878.9.

[53 FR 23872, June 24, 1988, as amended at 54 FR 13828, Apr. 5, 1989; 59 FR 63010, Dec. 7, 1994; 66 FR 38803, July 25, 2001]

### § 878.5910 Pneumatic tourniquet.

(a) *Identification.* A pneumatic tourniquet is an air-powered device consisting of a pressure-regulating unit, connecting tubing, and an inflatable cuff. The cuff is intended to be wrapped around a patient's limb and inflated to

reduce or totally occlude circulation during surgery.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in §878.9.

[53 FR 23872, June 24, 1988, as amended at 61 FR 1123, Jan. 16, 1996; 66 FR 38803, July 25, 2001]

# PART 880—GENERAL HOSPITAL AND PERSONAL USE DEVICES

## Subpart A—General Provisions

Sec.
880.1 Scope.
880.3 Effective dates of requirement for premarket approval.
880.9 Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).

## Subpart B [Reserved]

## Subpart C—General Hospital and Personal Use Monitoring Devices

880.2200 Liquid crystal forehead temperature strip.
880.2400 Bed-patient monitor.
880.2420 Electronic monitor for gravity flow infusion systems.
880.2460 Electrically powered spinal fluid pressure monitor.
880.2500 Spinal fluid manometer.
880.2700 Stand-on patient scale.
880.2720 Patient scale.
880.2740 Surgical sponge scale.
880.2800 Sterilization process indicator.
880.2900 Clinical color change thermometer.
880.2910 Clinical electronic thermometer.
880.2920 Clinical mercury thermometer.
880.2930 Apgar timer.

## Subparts D–E [Reserved]

## Subpart F—General Hospital and Personal Use Therapeutic Devices

880.5025 I.V. container.
880.5045 Medical recirculating air cleaner.
880.5075 Elastic bandage.
880.5090 Liquid bandage.
880.5100 AC-powered adjustable hospital bed.
880.5110 Hydraulic adjustable hospital bed.
880.5120 Manual adjustable hospital bed.
880.5130 Infant radiant warmer.
880.5140 Pediatric hospital bed.
880.5150 Nonpowered flotation therapy mattress.
880.5160 Therapeutic medical binder.
880.5180 Burn sheet.
880.5200 Intravascular catheter.
880.5210 Intravascular catheter securement device.
880.5240 Medical adhesive tape and adhesive bandage.
880.5270 Neonatal eye pad.
880.5300 Medical absorbent fiber.
880.5400 Neonatal incubator.
880.5410 Neonatal transport incubator.
880.5420 Pressure infusor for an I.V. bag.
880.5430 Nonelectrically powered fluid injector.
880.5440 Intravascular administration set.
880.5450 Patient care reverse isolation chamber.
880.5475 Jet lavage.
880.5500 AC-powered patient lift.
880.5510 Non-AC-powered patient lift.
880.5550 Alternating pressure air flotation mattress.
880.5560 Temperature regulated water mattress.
880.5570 Hypodermic single lumen needle.
880.5580 Acupuncture needle.
880.5630 Nipple shield.
880.5640 Lamb feeding nipple.
880.5680 Pediatric position holder.
880.5700 Neonatal phototherapy unit.
880.5725 Infusion pump.
880.5740 Suction snakebite kit.
880.5760 Chemical cold pack snakebite kit.
880.5780 Medical support stocking.
880.5820 Therapeutic scrotal support.
880.5860 Piston syringe.
880.5950 Umbilical occlusion device.
880.5960 Lice removal kit.
880.5965 Subcutaneous, implanted, intravascular infusion port and catheter.
880.5970 Percutaneous, implanted, long-term intravascular catheter.

## Subpart G—General Hospital and Personal Use Miscellaneous Devices

880.6025 Absorbent tipped applicator.
880.6050 Ice bag.
880.6060 Medical disposable bedding.
880.6070 Bed board.
880.6080 Cardiopulmonary resuscitation board.
880.6085 Hot/cold water bottle.
880.6100 Ethylene oxide gas aerator cabinet.
880.6140 Medical chair and table.
880.6150 Ultrasonic cleaner for medical instruments.
880.6175 [Reserved]
880.6185 Cast cover.
880.6190 Mattress cover for medical purposes.
880.6200 Ring cutter.
880.6230 Tongue depressor.
880.6250 Patient examination glove.
880.6260 Filtering facepiece respirator for use by the general public in public health medical emergencies.
880.6265 Examination gown.
880.6280 Medical insole.