

**§ 878.5650 Topical oxygen chamber for extremities.**

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

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 878.3.

**§ 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. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

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

**§ 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. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[53 FR 23872, June 24, 1988, as amended at 61 FR 1123, Jan. 16, 1996]

**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.

**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.