

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]

§ 878.5650 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.

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 infuser for an I.V. bag.

880.5430 Nonelectrically powered fluid injector.

880.5440 Intravascular administration set.