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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.


**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.
880.2520 Stand-on patient scale.
880.2720 Patient scale.
880.2740 Surgical sponge scale.
880.2800 Sterilization process indicator.
880.2900 Clinical color change thermometer.
880.2920 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 stockinet.
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.
880.6280 Filtering facepiece respirator for use by the general public in public health medical emergencies.
880.6285 Examination gown.
880.6280 Medical insole.