

§ 880.5400

concerning records, and § 820.198, with respect to complaint files.

[45 FR 69682-69737, Oct. 21, 1980, as amended at 66 FR 38804, July 25, 2001]

§ 880.5400 Neonatal incubator.

(a) *Identification.* A neonatal incubator is a device consisting of a rigid boxlike enclosure in which an infant may be kept in a controlled environment for medical care. The device may include an AC-powered heater, a fan to circulate the warmed air, a container for water to add humidity, a control valve through which oxygen may be added, and access ports for nursing care.

(b) *Classification.* Class II (performance standards).

§ 880.5410 Neonatal transport incubator.

(a) *Identification.* A neonatal transport incubator is a device consisting of a portable rigid boxlike enclosure with insulated walls in which an infant may be kept in a controlled environment while being transported for medical care. The device may include straps to secure the infant, a battery-operated heater, an AC-powered battery charger, a fan to circulate the warmed air, a container for water to add humidity, and provision for a portable oxygen bottle.

(b) *Classification.* Class II (performance standards).

§ 880.5420 Pressure infusor for an I.V. bag.

(a) *Identification.* A pressure infusor for an I.V. bag is a device consisting of an inflatable cuff which is placed around an I.V. bag. When the device is inflated, it increases the pressure on the I.V. bag to assist the infusion of the fluid.

(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 § 880.9.

[45 FR 69682-69737, Oct. 21, 1980, as amended at 65 FR 2318, Jan. 14, 2000]

21 CFR Ch. I (4-1-03 Edition)

§ 880.5430 Nonelectrically powered fluid injector.

(a) *Identification.* A nonelectrically powered fluid injector is a nonelectrically powered device used by a health care provider to give a hypodermic injection by means of a narrow, high velocity jet of fluid which can penetrate the surface of the skin and deliver the fluid to the body. It may be used for mass inoculations.

(b) *Classification.* Class II (performance standards).

§ 880.5440 Intravascular administration set.

(a) *Identification.* An intravascular administration set is a device used to administer fluids from a container to a patient's vascular system through a needle or catheter inserted into a vein. The device may include the needle or catheter, tubing, a flow regulator, a drip chamber, an infusion line filter, an I.V. set stopcock, fluid delivery tubing, connectors between parts of the set, a side tube with a cap to serve as an injection site, and a hollow spike to penetrate and connect the tubing to an I.V. bag or other infusion fluid container.

(b) *Classification.* Class II (special controls). The special control for pharmacy compounding systems within this classification is the FDA guidance document entitled "Class II Special Controls Guidance Document: Pharmacy Compounding Systems; Final Guidance for Industry and FDA Reviewers." Pharmacy compounding systems classified within the intravascular administration set are exempt from the premarket notification procedures in subpart E of this part and subject to the limitations in § 880.9.

[45 FR 69682-69737, Oct. 21, 1980, as amended at 66 FR 15798, Mar. 21, 2001]

§ 880.5450 Patient care reverse isolation chamber.

(a) *Identification.* A patient care reverse isolation chamber is a device consisting of a roomlike enclosure designed to prevent the entry of harmful airborne material. This device protects a patient who is undergoing treatment

Food and Drug Administration, HHS

§ 880.5570

for burns or is lacking a normal immunosuppressive defense due to therapy or congenital abnormality. The device includes fans and air filters which maintain an atmosphere of clean air at a pressure greater than the air pressure outside the enclosure.

(b) *Classification*. Class II (performance standards).

§ 880.5475 Jet lavage.

(a) *Identification*. A jet lavage is a device used to clean a wound by a pulsatile jet of sterile fluid. The device consists of the pulsing head, tubing to connect to a container of sterile fluid, and a means of propelling the fluid through the tubing, such as an electric roller pump.

(b) *Classification*. Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 880.9.

[45 FR 69682-69737, Oct. 21, 1980, as amended at 63 FR 59229, Nov. 3, 1998]

§ 880.5500 AC-powered patient lift.

(a) *Identification*. An AC-powered lift is an electrically powered device either fixed or mobile, used to lift and transport patients in the horizontal or other required position from one place to another, as from a bed to a bath. The device includes straps and slings to support the patient.

(b) *Classification*. Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 880.9.

[45 FR 69682-69737, Oct. 21, 1980, as amended at 63 FR 59229, Nov. 3, 1998]

§ 880.5510 Non-AC-powered patient lift.

(a) *Identification*. A non-AC-powered patient lift is a hydraulic, battery, or mechanically powered device, either fixed or mobile, used to lift and transport a patient in the horizontal or other required position from one place to another, as from a bed to a bath. The device includes straps and a sling to support the patient.

(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 § 880.9.

[45 FR 69682-69737, Oct. 21, 1980, as amended at 54 FR 25050, June 12, 1989; 66 FR 38804, July 25, 2001]

§ 880.5550 Alternating pressure air flotation mattress.

(a) *Identification*. An alternating pressure air flotation mattress is a device intended for medical purposes that consists of a mattress with multiple air cells that can be filled and emptied in an alternating pattern by an associated control unit to provide regular, frequent, and automatic changes in the distribution of body pressure. The device is used to prevent and treat decubitus ulcers (bed sores).

(b) *Classification*. Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 880.9.

[45 FR 69682-69737, Oct. 21, 1980, as amended at 63 FR 59229, Nov. 3, 1998]

§ 880.5560 Temperature regulated water mattress.

(a) *Identification*. A temperature regulated water mattress is a device intended for medical purposes that consists of a mattress of suitable size, filled with water which can be heated or in some cases cooled. The device includes electrical heating and water circulating components, and an optional cooling component. The temperature control may be manual or automatic.

(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 § 880.9.

[45 FR 69682-69737, Oct. 21, 1980, as amended at 61 FR 1123, Jan. 16, 1996; 66 FR 38804, July 25, 2001]

§ 880.5570 Hypodermic single lumen needle.

(a) *Identification*. A hypodermic single lumen needle is a device intended to inject fluids into, or withdraw fluids from, parts of the body below the surface of the skin. The device consists of a metal tube that is sharpened at one end and at the other end joined to a female connector (hub) designed to mate