

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