§ 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.


§ 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.


§ 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 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 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.


§ 880.5550  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.


§ 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
with a male connector (nozzle) of a piston syringe or an intravascular administration set.

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

§ 880.5580 Acupuncture needle.

(a) Identification. An acupuncture needle is a device intended to pierce the skin in the practice of acupuncture. The device consists of a solid, stainless steel needle. The device may have a handle attached to the needle to facilitate the delivery of acupuncture treatment.

(b) Classification. Class II (special controls). Acupuncture needles must comply with the following special controls:

1. Labeling for single use only and conformance to the requirements for prescription devices set out in 21 CFR 801.109.
2. Device material biocompatibility.

§ 880.5630 Nipple shield.

(a) Identification. A nipple shield is a device consisting of a cover used to protect the nipple of a nursing woman. This generic device does not include nursing pads intended solely to protect the clothing of a nursing woman from milk.

(b) Classification. Class I (general controls). The device is exempt from the good manufacturing practice regulation in part 820 of this chapter, with the exception of § 820.180, with respect to complaint files.

§ 880.5640 Lamb feeding nipple.

(a) Identification. A lamb feeding nipple is a device intended for use as a feeding nipple for infants with oral or facial abnormalities.

(b) Classification. Class I (general controls). The device is exempt from the good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of § 820.180, with respect to complaint files.

§ 880.5680 Pediatric position holder.

(a) Identification. A pediatric position holder is a device used to hold an infant or a child in a desired position for therapeutic or diagnostic purposes, e.g., in a crib under a radiant warmer, or to restrain a child while an intravascular injection is administered.

(b) Classification. Class I (general controls). The device is exempt from the good manufacturing practice regulation in part 820 of this chapter, with the exception of § 820.180, with respect to complaint files.

§ 880.5700 Neonatal phototherapy unit.

(a) Identification. A neonatal phototherapy unit is a device used to treat or prevent hyperbilirubinemia (elevated serum bilirubin level). The device consists of one or more lamps that emit a specific spectral band of light, under which an infant is placed for therapy. This generic type of device may include supports for the patient and equipment and component parts.

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

§ 880.5725 Infusion pump.

(a) Identification. An infusion pump is a device used in a health care facility to pump fluids into a patient in a controlled manner. The device may use a piston pump, a roller pump, or a peristaltic pump and may be powered electrically or mechanically. The device may also operate using a constant force to propel the fluid through a narrow tube which determines the flow rate. The device may include means to detect a fault condition, such as air in, or blockage of, the infusion line and to activate an alarm.