Food and Drug Administration, HHS

part 820 of this chapter, with the exception of §820.180 of this chapter, with respect to general requirements concerning records, and §820.198 of this chapter, with respect to complaint files.


§ 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 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).

§ 880.5410 Neonatal transport incubator.

(a) Identification. A neonatal transport incubator is a device consisting of a portable rigid boxlike enclosure with

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