Food and Drug Administration, HHS

§ 880.5300 Medical absorbent fiber.

(a) Identification. A medical absorbent fiber is a device intended for medical purposes that is made from cotton or synthetic fiber in the shape of a ball or a pad and that is used for applying medication to, or absorbing small amounts of body fluids from, a patient’s body surface. Absorbent fibers intended solely for cosmetic purposes are not included in this generic device category.

(b) Classification. Class I (general controls).

§ 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, 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 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).

§ 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