§ 880.5180 Burn sheet.

(a) Identification. A burn sheet is a device made of a porous material that is wrapped around a burn victim to retain body heat, to absorb wound exudate, and to serve as a barrier against contaminants.

(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.

§ 880.5200 Intravascular catheter.

(a) Identification. An intravascular catheter is a device that consists of a slender tube and any necessary connecting fittings and that is inserted into the patient’s vascular system for short term use (less than 30 days) to sample blood, monitor blood pressure, or administer fluids intravenously. The device may be constructed of metal, rubber, plastic, or a combination of these materials.

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

§ 880.5210 Intravascular catheter securement device.

(a) Identification. An intravascular catheter securement device is a device with an adhesive backing that is placed over a needle or catheter and is used to keep the hub of the needle or the catheter flat and securely anchored to the skin.

(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.

§ 880.5240 Medical adhesive tape and adhesive bandage.

(a) Identification. A medical adhesive tape or adhesive bandage is a device intended for medical purposes that consists of a strip of fabric material or plastic, coated on one side with an adhesive, and may include a pad of surgical dressing without a disinfectant. The device is used to cover and protect wounds, to hold together the skin edges of a wound, to support an injured part of the body, or to secure objects to the skin.

(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.

§ 880.5270 Neonatal eye pad.

(a) Identification. A neonatal eye pad is an opaque device used to cover and protect the eye of an infant during therapeutic procedures, such as phototherapy.

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

§ 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). 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. If the device is not labeled or otherwise represented as sterile, it is also exempt from the current good manufacturing practice requirements of the quality system regulation in 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.

§ 880.5320 Medical gauze bandage.

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

(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.

§ 880.5330 Medical cast and splint.

(a) Identification. A medical cast or splint is a device made of a material that is molded or shaped to fit over a body part, and that is used to support, immobilize, or protect a body part.

(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.

§ 880.5340 Medical thermometers.

(a) Identification. A medical thermometer is a device that is used to measure, record, or display body temperature.

(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.

§ 880.5350 Medical restraints.

(a) Identification. Medical restraints are a device that is used to restrict or limit movement of a body part.

(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.