

Food and Drug Administration, HHS

§ 880.2740

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 59 FR 63010, Dec. 7, 1994; 66 FR 38803, July 25, 2001]

§ 880.2420 Electronic monitor for gravity flow infusion systems.

(a) *Identification.* An electronic monitor for gravity flow infusion systems is a device used to monitor the amount of fluid being infused into a patient. The device consists of an electronic transducer and equipment for signal amplification, conditioning, and display.

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

§ 880.2460 Electrically powered spinal fluid pressure monitor.

(a) *Identification.* An electrically powered spinal fluid pressure monitor is an electrically powered device used to measure spinal fluid pressure by the use of a transducer which converts spinal fluid pressure into an electrical signal. The device includes signal amplification, conditioning, and display equipment.

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

§ 880.2500 Spinal fluid manometer.

(a) *Identification.* A spinal fluid manometer is a device used to measure spinal fluid pressure. The device uses a hollow needle, which is inserted into the spinal column fluid space, to connect the spinal fluid to a graduated column so that the pressure can be measured by reading the height of the fluid.

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

§ 880.2700 Stand-on patient scale.

(a) *Identification.* A stand-on patient scale is a device intended for medical purposes that is used to weigh a patient who is able to stand on the scale platform.

(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. The device also is exempt from the current good manufacturing practice regula-

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

[45 FR 69682-69737, Oct. 21, 1980, as amended at 66 FR 38803, July 25, 2001]

§ 880.2720 Patient scale.

(a) *Identification.* A patient scale is a device intended for medical purposes that is used to measure the weight of a patient who cannot stand on a scale. This generic device includes devices placed under a bed or chair to weigh both the support and the patient, devices where the patient is lifted by a sling from a bed to be weighed, and devices where the patient is placed on the scale platform to be weighed. The device may be mechanical, battery powered, or AC-powered and may include transducers, electronic signal amplification, conditioning and display equipment.

(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 38803, July 25, 2001]

§ 880.2740 Surgical sponge scale.

(a) *Identification.* A surgical sponge scale is a nonelectrically powered device used to weigh surgical sponges that have been used to absorb blood during surgery so that, by comparison with the known dry weight of the sponges, an estimate may be made of the blood lost by the patient during surgery.

(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. The device also is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

[45 FR 69682-69737, Oct. 21, 1980, as amended at 66 FR 38804, July 25, 2001]