consists of a stiff board used to increase the firmness of a bed.

(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 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, with respect to general requirements concerning records, and §820.198, with respect to complaint files.


§ 880.6080 Cardiopulmonary resuscitation board.

(a) Identification. A cardiopulmonary resuscitation board is a device consisting of a rigid board which is placed under a patient to act as a support during cardiopulmonary resuscitation.

(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 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, with respect to general requirements concerning records, and §820.198, with respect to complaint files.


§ 880.6085 Hot/cold water bottle.

(a) Identification. A hot/cold water bottle is a device intended for medical purposes that is in the form of a container intended to be filled with hot or cold water to apply heat or cold to an area of the body.

(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 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, with respect to general requirements concerning records, and §820.198, with respect to complaint files.


§ 880.6150 Ultrasonic cleaner for medical instruments.

(a) Identification. An ultrasonic cleaner for medical instruments is a device