good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of §820.180, regarding general requirements concerning records and §820.198, regarding complaint files.


Subpart E [Reserved]

Subpart F—Physical Medicine Therapeutic Devices

§890.5050 Daily activity assist device.

(a) Identification. A daily activity assist device is a modified adaptor or utensil (e.g., a dressing, grooming, recreational activity, transfer, eating, or homemaking aid) that is intended for medical purposes to assist a patient to perform a specific function.

(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 §890.9. If the device is not labeled or otherwise represented as sterile, 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, regarding general requirements concerning records and §820.198, regarding complaint files.


§890.5100 Immersion hydrobath.

(a) Identification. An immersion hydrobath is a device intended for medical purposes that consists of water agitators and that may include a tub to be filled with water for use in external hydrotherapy to relieve pain or pruritis and to accelerate the healing of inflamed or traumatized tissues of the perianal and perineal areas.

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

§890.5110 Paraffin bath.

(a) Identification. A paraffin bath is a device intended for medical purposes that consists of a tub to be filled with liquid paraffin (wax) and maintained at an elevated temperature in which the patient’s appendages (e.g., hands or fingers) are placed to relieve pain and stiffness.

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

§890.5125 Nonpowered sitz bath.

(a) Identification. A nonpowered sitz bath is a device intended for medical purposes that consists of a tub to be filled with water for use in external hydrotherapy to relieve pain or pruritis and to accelerate the healing of inflamed or traumatized tissues of the perianal and perineal areas.

(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 §890.9. 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, regarding general requirements concerning records and §820.198, regarding complaint files.


§890.5150 Powered patient transport.

(a) Powered patient stairway chair lifts—(1) Identification. A powered patient stairway chair lift is a motorized lift equipped with a seat and permanently mounted in one location that is intended for use in mitigating mobility impairment caused by injury or other disease by moving a person up and down a stairway.

(2) Classification. Class II. The stairway chair lift is exempt from premarket notification procedures in subpart E of part 807 of this chapter, subject to §890.9 and the following conditions for exemption:

(i) Appropriate analysis and nonclinical testing (such as that outlined in the currently FDA-recognized edition of American Society of Mechanical Engineers (ASME) A18.1 “Safety Standard
§ 890.5160  Air-fluidized bed.

(a) Identification. An air-fluidized bed is a device employing the circulation of filtered air through ceramic spherules (small, round ceramic objects) that is intended for medical purposes to treat or prevent bedsores, to treat severe or extensive burns, or to aid circulation.

(b) Classification. Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 890.9.

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