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.

[48 FR 53047, Nov. 23, 1983, as amended at 66 FR 38817, July 25, 2001]

§ 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. The water temperature may be measured by a gauge. It is used in hydrotherapy to relieve pain and itching and as an aid in the healing process of inflamed and traumatized tissue, and it serves as a setting for removal of contaminated tissue.

(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.

[48 FR 53047, Nov. 23, 1983, as amended at 54 FR 25052, June 12, 1989; 66 FR 38818, July 25, 2001]

§ 890.5150 Powered patient transport.

(a) *Identification.* A powered patient transport is a motorized device intended for medical purposes to assist transfers of patients to and from the bath, beds, chairs, treatment modalities, transport vehicles, and up and down flights of stairs. This generic type of device does not include motorized threewheeled vehicles or wheelchairs.

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

§ 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.

[48 FR 53047, Nov. 23, 1983, as amended at 63 FR 59231, Nov. 3, 1998]

§ 890.5170 Powered flotation therapy bed.

(a) *Identification.* A powered flotation therapy bed is a device that is equipped with a mattress that contains a large volume of constantly moving water, air, mud, or sand. It is intended for medical purposes to treat or prevent a patient's bedsores, to treat severe or extensive burns, or to aid circulation. The mattress may be electrically heated.

(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.

[48 FR 53047, Nov. 23, 1983, as amended at 63 FR 59231, Nov. 3, 1998]