

§ 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) *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 for Platform Lifts and Stairway Chair Lifts”) must demonstrate that the safety controls are adequate to prevent a free fall of the chair in the event of a device failure;

(ii) Appropriate analysis and nonclinical testing must demonstrate the ability of the device, including armrests, to withstand the rated load with an appropriate factor of safety;

(iii) Appropriate restraints must be provided to prevent the user from fall-

ing from the device (such as that outlined in the currently FDA-recognized edition of ASME A18.1 “Safety Standard for Platform Lifts and Stairway Chair Lifts”);

(iv) Appropriate analysis and nonclinical testing (such as that outlined in the currently FDA-recognized editions of AAMI/ANSI/IEC 60601-1-2, “Medical Electrical Equipment—Part 1-2: General Requirements for Safety—Collateral Standard: Electromagnetic Compatibility—Requirements and Tests,” and ASME A18.1 “Safety Standard for Platform Lifts and Stairway Chair Lifts”) must validate electromagnetic compatibility and electrical safety; and

(v) Appropriate analysis and nonclinical testing must demonstrate the resistance of the device upholstery to ignition.

(b) *All other powered patient transport—(1) Identification.* A powered patient transport is a motorized device intended for use in mitigating mobility impairment caused by injury or other disease by moving a person from one location or level to another, such as up and down flights of stairs (e.g., attendant-operated portable stair-climbing chairs). This generic type of device does not include motorized three-wheeled vehicles or wheelchairs.

(2) *Classification.* Class II.

[78 FR 14017, Mar. 4, 2013]

§ 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