

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 66 FR 38817, July 25, 2001]

§ 890.3800 Motorized three-wheeled vehicle.

(a) *Identification.* A motorized three-wheeled vehicle is a gasoline-fueled or battery-powered device intended for medical purposes that is used for outside transportation by disabled persons.

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

§ 890.3825 Mechanical walker.

(a) *Identification.* A mechanical walker is a four-legged device with a metal frame intended for medical purposes to provide moderate weight support while walking. It is used by disabled persons who lack strength, good balance, or endurance.

(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 66 FR 38817, July 25, 2001]

§ 890.3850 Mechanical wheelchair.

(a) *Identification.* A mechanical wheelchair is a manually operated device with wheels that is intended for medical purposes to provide mobility to persons restricted to a sitting position.

(b) *Classification.* Class I (general controls).

§ 890.3860 Powered wheelchair.

(a) *Identification.* A powered wheelchair is a battery-operated device with

wheels that is intended for medical purposes to provide mobility to persons restricted to a sitting position.

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

§ 890.3880 Special grade wheelchair.

(a) *Identification.* A special grade wheelchair is a device with wheels that is intended for medical purposes to provide mobility to persons restricted to a sitting position. It is intended to be used in all environments for long-term use, e.g., for paraplegics, quadraplegics, and amputees.

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

§ 890.3890 Stair-climbing wheelchair.

(a) *Identification.* A stair-climbing wheelchair is a device with wheels that is intended for medical purposes to provide mobility to persons restricted to a sitting position. The device is intended to climb stairs by means of two endless belt tracks that are lowered from under the chair and adjusted to the angle of the stairs.

(b) *Classification.* Class III (premarket approval).

(c) *Date PMA or notice of completion of a PDP is required.* A PMA or notice of completion of a PDP for a device described in paragraph (b) of this section is required to be filed with the Food and Drug Administration on or before July 12, 2000, for any stair-climbing wheelchair that was in commercial distribution before May 28, 1976, or that has, on or before July 12, 2000, been found to be substantially equivalent to a stair-climbing wheelchair that was in commercial distribution before May 28, 1976. Any other stair-climbing wheelchair shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

[48 FR 53047, Nov. 23, 1983, as amended at 52 FR 17742, May 11, 1987; 52 FR 22577, June 12, 1987; 65 FR 19834, Apr. 13, 2000]

§ 890.3900 Standup wheelchair.

(a) *Identification.* A standup wheelchair is a device with wheels that is intended for medical purposes to provide mobility to persons restricted to a sitting position. The device incorporates