

§ 890.3420

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

§ 890.3420 External limb prosthetic component.

(a) *Identification.* An external limb prosthetic component is a device intended for medical purposes that, when put together with other appropriate components, constitutes a total prosthesis. Examples of external limb prosthetic components include the following: Ankle, foot, hip, knee, and socket components; mechanical or powered hand, hook, wrist unit, elbow joint, and shoulder joint components; and cable and prosthesis suction valves.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807. The device also is exempt from the current good manufacturing practice regulations in part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 890.3475 Limb orthosis.

(a) *Identification.* A limb orthosis (brace) is a device intended for medical purposes that is worn on the upper or lower extremities to support, to correct, or to prevent deformities or to align body structures for functional improvement. Examples of limb orthoses include the following: A whole limb and joint brace, a hand splint, an elastic stocking, a knee cage, and a corrective shoe.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807. The device also is exempt from the current good manufacturing practice regulations in part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 890.3490 Truncal orthosis.

(a) *Identification.* A truncal orthosis is a device intended for medical purposes to support or to immobilize fractures, strains, or sprains of the neck or trunk of the body. Examples of truncal

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orthoses are the following: Abdominal, cervical, cervical-thoracic, lumbar, lumbo-sacral, rib fracture, sacroiliac, and thoracic orthoses and clavicle splints.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807. The device also is exempt from the current good manufacturing practice regulations in part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 890.3500 External assembled lower limb prosthesis.

(a) *Identification.* An external assembled lower limb prosthesis is a device that is intended for medical purposes and is a preassembled external artificial limb for the lower extremity. Examples of external assembled lower limb prostheses are the following: Knee/shank/ankle/foot assembly and thigh/knee/shank/ankle/foot assembly.

(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]

§ 890.3520 Plinth.

(a) *Identification.* A plinth is a flat, padded board with legs that is intended for medical purposes. A patient is placed on the device for treatment or examination.

(b) *Classification.* Class I (general controls). This device is exempt from the premarket notification procedure in subpart E of part 807. The device is also exempt from the current good manufacturing practice regulations in part 820, with the exception of § 820.180, with respect to general requirements concerning records and § 820.198 with respect to complaint files.

§ 890.3610 Rigid pneumatic structure orthosis.

(a) *Identification.* A rigid pneumatic structure orthosis is a device intended for medical purposes to provide whole body support by means of a pressurized suit to help thoracic paraplegics walk.

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

(c) *Date PMA or notice of completion of a PDP is required*. A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any rigid pneumatic structure orthosis that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to a rigid pneumatic structure orthosis that was in commercial distribution before May 28, 1976. Any other rigid pneumatic structure orthosis shall have an approved PMA or a 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; 61 FR 50711, Sept. 27, 1996]

§ 890.3640 Arm sling.

(a) *Identification*. An arm sling is a device intended for medical purposes to immobilize the arm, by means of a fabric band suspended from around the neck.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807. The device also is exempt from the current good manufacturing practice regulations in part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 890.3665 Congenital hip dislocation abduction splint.

(a) *Identification*. A congenital hip dislocation abduction splint is a device intended for medical purposes to stabilize the hips of a young child with dislocated hips in an abducted position (away from the midline).

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807. The device also is exempt from the current good manufacturing practice regulations in part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 890.3675 Denis Brown splint.

(a) *Identification*. A Denis Brown splint is a device intended for medical purposes to immobilize the foot. It is used on young children with tibial torsion (excessive rotation of the lower leg) or club foot.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807. The device also is exempt from the current good manufacturing practice regulations in part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 890.3690 Powered wheeled stretcher.

(a) *Identification*. A powered wheeled stretcher is a battery-powered table with wheels that is intended for medical purposes for use by patients who are unable to propel themselves independently and who must maintain a prone or supine position for prolonged periods because of skin ulcers or contractures (muscle contractions).

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

§ 890.3700 Nonpowered communication system.

(a) *Identification*. A nonpowered communication system is a mechanical device intended for medical purposes that is used to assist a patient in communicating when physical impairment prevents writing, telephone use, reading, or talking. Examples of nonpowered communications systems include an alphabet board and a page turner.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter. The device is also exempt from the current good manufacturing practice regulations 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]