

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

[52 FR 33355, Sept. 2, 1987, as amended at 53 FR 35607, Sept. 14, 1988]

§ 886.5915 Optical vision aid.

(a) *Identification.* An optical vision aid is a device that consists of a magnifying lens with an accompanying AC-powered or battery-powered light source intended for use by a patient who has impaired vision to increase the apparent size of object detail.

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

[55 FR 48443, Nov. 20, 1990, as amended at 59 FR 63014, Dec. 7, 1994]

§ 886.5916 Rigid gas permeable contact lens.

(a) *Identification.* A rigid gas permeable contact lens is a device intended to be worn directly against the cornea of the eye to correct vision conditions. The device is made of various materials, such as cellulose acetate butyrate, polyacrylate-silicone, or silicone elastomers, whose main polymer molecules generally do not absorb or attract water.

(b) *Classification.* (1) Class II if the device is intended for daily wear only.

(2) Class III if the device is intended for extended wear.

(c) *Date PMA or notice of completion of a PDP is required.* As of May 28, 1976, an approval under section 515 of the act is required before a device described in

paragraph (b)(2) of this section may be commercially distributed. See § 886.3.

[52 FR 33355, Sept. 2, 1987, as amended at 59 FR 10284, Mar. 4, 1994]

§ 886.5918 Rigid gas permeable contact lens care products.

(a) *Identification.* A rigid gas permeable contact lens care product is a device intended for use in the cleaning, conditioning, rinsing, lubricating/re-wetting, or storing of a rigid gas permeable contact lens. This includes all solutions and tablets used together with rigid gas permeable contact lenses.

(b) *Classification.* Class II (Special Controls) Guidance Document: "Guidance for Industry Premarket Notification (510(k)) Guidance Document for Contact Lens Care Products."

[62 FR 30987, June 6, 1997]

§ 886.5925 Soft (hydrophilic) contact lens.

(a) *Identification.* A soft (hydrophilic) contact lens is a device intended to be worn directly against the cornea and adjacent limbal and scleral areas of the eye to correct vision conditions or act as a therapeutic bandage. The device is made of various polymer materials the main polymer molecules of which absorb or attract a certain volume (percentage) of water.

(b) *Classification.* (1) Class II if the device is intended for daily wear only.

(2) Class III if the device is intended for extended wear.

(c) *Date PMA or notice of completion of a PDP is required.* As of May 28, 1976, an approval under section 515 of the act is required before a device described in paragraph (b)(2) of this section may be commercially distributed. See § 886.3.

[52 FR 33355, Sept. 2, 1987, as amended at 59 FR 10284, Mar. 4, 1994]

§ 886.5928 Soft (hydrophilic) contact lens care products.

(a) *Identification.* A soft (hydrophilic) contact lens care product is a device intended for use in the cleaning, rinsing, disinfecting, lubricating/re-wetting, or storing of a soft (hydrophilic) contact lens. This includes all solutions

and tablets used together with soft (hydrophilic) contact lenses and heat disinfecting units intended to disinfect a soft (hydrophilic) contact lens by means of heat.

(b) *Classification.* Class II (Special Controls) Guidance Document: “Guidance for Industry Premarket Notification (510(k)) Guidance Document for Contact Lens Care Products.”

[62 FR 30988, June 6, 1997]

§ 886.5933 [Reserved]

PART 888—ORTHOPEDIC DEVICES

Subpart A—General Provisions

Sec.

- 888.1 Scope.
- 888.3 Effective dates of requirement for premarket approval.
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Subpart B—Diagnostic Devices

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Subpart D—Prosthetic Devices

- 888.3000 Bone cap.
- 888.3010 Bone fixation cerclage.
- 888.3015 Bone heterograft.
- 888.3020 Intramedullary fixation rod.
- 888.3025 Passive tendon prosthesis.
- 888.3027 Polymethylmethacrylate (PMMA) bone cement.
- 888.3030 Single/multiple component metallic bone fixation appliances and accessories.
- 888.3040 Smooth or threaded metallic bone fixation fastener.
- 888.3050 Spinal interlaminar fixation orthosis.
- 888.3060 Spinal intervertebral body fixation orthosis.
- 888.3100 Ankle joint metal/composite semi-constrained cemented prosthesis.
- 888.3110 Ankle joint metal/polymer semi-constrained cemented prosthesis.
- 888.3120 Ankle joint metal/polymer non-constrained cemented prosthesis.
- 888.3150 Elbow joint metal/metal or metal/polymer constrained cemented prosthesis.
- 888.3160 Elbow joint metal/polymer semi-constrained cemented prosthesis.

- 888.3170 Elbow joint radial (hemi-elbow) polymer prosthesis.
- 888.3180 Elbow joint humeral (hemi-elbow) metallic uncemented prosthesis.
- 888.3200 Finger joint metal/metal constrained uncemented prosthesis.
- 888.3210 Finger joint metal/metal constrained cemented prosthesis.
- 888.3220 Finger joint metal/polymer constrained cemented prosthesis.
- 888.3230 Finger joint polymer constrained prosthesis.
- 888.3300 Hip joint metal constrained cemented or uncemented prosthesis.
- 888.3310 Hip joint metal/polymer constrained cemented or uncemented prosthesis.
- 888.3320 Hip joint metal/metal semi-constrained, with a cemented acetabular component, prosthesis.
- 888.3330 Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis.
- 888.3340 Hip joint metal/composite semi-constrained cemented prosthesis.
- 888.3350 Hip joint metal/polymer semi-constrained cemented prosthesis.
- 888.3353 Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis.
- 888.3358 Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis.
- 888.3360 Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis.
- 888.3370 Hip joint (hemi-hip) acetabular metal cemented prosthesis.
- 888.3380 Hip joint femoral (hemi-hip) trunnion-bearing metal/polyacetal cemented prosthesis.
- 888.3390 Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis.
- 888.3400 Hip joint femoral (hemi-hip) metallic resurfacing prosthesis.
- 888.3410 Hip joint metal/polymer semi-constrained resurfacing cemented prosthesis.
- 888.3480 Knee joint femorotibial metallic constrained cemented prosthesis.
- 888.3490 Knee joint femorotibial metal/composite non-constrained cemented prosthesis.
- 888.3500 Knee joint femorotibial metal/composite semi-constrained cemented prosthesis.
- 888.3510 Knee joint femorotibial metal/polymer constrained cemented prosthesis.
- 888.3520 Knee joint femorotibial metal/polymer non-constrained cemented prosthesis.
- 888.3530 Knee joint femorotibial metal/polymer semi-constrained cemented prosthesis.
- 888.3540 Knee joint patellofemoral polymer/metal semi-constrained cemented prosthesis.