

(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]

§ 886.5900 Electronic vision aid.

(a) *Identification*. An electronic vision aid is an AC-powered or battery-powered device that consists of an electronic sensor/transducer intended for use by a patient who has impaired vision or blindness to translate visual images of objects into tactile or auditory signals.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

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

§ 886.5910 Image intensification vision aid.

(a) *Identification*. An image intensification vision aid is a battery-powered device intended for use by a patient who has limited dark adaptation or impaired vision to amplify ambient light.

(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.

§ 886.5925

(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/rewetting, 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]

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§ 886.5933 [Reserved]

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- 888.3040 Smooth or threaded metallic bone fixation fastener.
- 888.3050 Spinal interlaminar fixation orthosis.
- 888.3060 Spinal intervertebral body fixation orthosis.
- 888.3070 Pedicle screw spinal system.
- 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/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.