Food and Drug Administration, HHS

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


§ 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 (general controls). 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, subject to the limitations in §886.9. The battery-powered 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, with respect to general requirements concerning records, and §820.198, with respect to complaint files.


§ 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 (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 §886.9.


§ 886.5890 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 (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 §886.9. 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, with respect to general requirements concerning records, and §820.198, with respect to complaint files.


§ 886.5870 Low-vision telescope.

(a) Identification. A low-vision telescope is a device that consists of an arrangement of lenses or mirrors intended for use by a patient who has impaired vision to increase the apparent size of objects. This generic type of device includes handheld or spectacle telescopes.

(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 §886.9.

(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.


§ 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/rewetting, 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.”


§ 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.


§ 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.”


§ 886.5933 [Reserved]

PART 888—ORTHOPEDIC DEVICES

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Subpart D—Prosthetic Devices

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888.3015 Bone heterograft.
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888.3030 Single/multiple component metallic bone fixation appliances and accessories.
888.3040 Smooth or threaded metallic bone fixation fastener.
888.3045 Resorbable calcium salt bone void filler device.
888.3050 Spinal interlaminal fixation orthosis.