§ 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 (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 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.

§ 886.5916 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, polycrystalline-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.

§ 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.”

§ 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.