§ 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, 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.