§ 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 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 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.”


§ 886.5925 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.