§ 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. (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 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

Subpart A—General Provisions

Sec.
888.1 Scope.
888.3 Effective dates of requirement for premarket approval.
888.5 Resurfacing technique.
888.6 Degree of constraint.
888.9 Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).

Subpart B—Diagnostic Devices

888.1100 Arthroscope.
888.1240 AC-powered dynamometer.
888.1250 Nonpowered dynamometer.
888.1500 Goniometer.
888.1520 Nonpowered goniometer.

Subpart C [Reserved]

Subpart D—Prosthetic Devices

888.3000 Bone cap.
888.3010 Bone fixation cerclage.
888.3015 Bone heterograft.
888.3020 Intramedullary fixation rod.
888.3025 Passive tendon prosthesis.
888.3027 Polymethylmethacrylate (PMMA) bone cement.
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 interlaminar fixation orthosis.