§ 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

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.
888.1590 Gonimeter.
888.1520 Nonpowered goniometer.

Subpart C [Reserved]

Subpart D—Prosthetic Devices

888.3000 Bone cap.
888.3010 Bone fixation cerclage.
888.3015 Bone heterograft.