§ 886.1910 Spectacle dissociation test system.

(a) Identification. A spectacle dissociation test system is an AC-powered or battery-powered device, such as a Lancaster test system, that consists of a light source and various filters, usually red or green filters, intended to subjectively measure imbalance of ocular muscles.

(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 battery-powered 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.


§ 886.1940 Tonometer sterilizer.

(a) Identification. A tonometer sterilizer is an AC-powered device intended to heat sterilize a tonometer (a device used to measure intraocular pressure).

(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 §886.9.


§ 886.1945 Transilluminator.

(a) Identification. A transilluminator is an AC-powered or battery-powered device that is a light source intended to transmit light through tissues to aid examination of patients.

(b) Classification. Class I for the battery-powered device. The battery-powered device is also exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in §886.9. Class II for the AC-powered device.


Subpart C [Reserved]

Subpart D—Prosthetic Devices

§ 886.3100 Ophthalmic tantalum clip.

(a) Identification. An ophthalmic tantalum clip is a malleable metallic device intended to be implanted permanently or temporarily to bring together the edges of a wound to aid healing or prevent bleeding from small blood vessels in the eye.

(b) Classification. Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to §886.9.


§ 886.3130 Ophthalmic conformer.

(a) Identification. An ophthalmic conformer is a device usually made of molded plastic intended to be inserted temporarily between the eyeball and eyelid to maintain space in the orbital cavity and prevent closure or adhesions...