§ 886.1450 Corneal radius measuring device.

(a) Identification. A corneal radius measuring device is an AC-powered device intended to measure corneal size by superimposing the image of the cornea on a scale at the focal length of the lens of a small, hand held, single tube penscope or eye gauge magnifier.

(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 the limitations in §886.9, only when the device does not include computer software in the unit or topographers.

§ 886.1460 Stereopsis measuring instrument.

(a) Identification. A stereopsis measuring instrument is a device intended to measure depth perception by illumination of objects placed on different planes.

(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 the limitations in §886.9. The 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.

§ 886.1500 Headband mirror.

(a) Identification. A headband mirror is a device intended to be strapped to the head of the user to reflect light for use in examination of the eye.

(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 the limitations in §886.9. The 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.

§ 886.1510 Eye movement monitor.

(a) Identification. An eye movement monitor is an AC-powered device with an electrode intended to measure and record ocular movements.

(b) Classification. Class II.

§ 886.1570 Ophthalmoscope.

(a) Identification. An ophthalmoscope is an AC-powered or battery-powered device containing illumination and viewing optics intended to examine the media (cornea, aqueous, lens, and vitreous) and the retina of the eye.

(b) Classification. Class II.

§ 886.1605 Perimeter.

(a) Identification. A perimeter is an AC-powered or manual device intended to determine the extent of the peripheral visual field of a patient. The device projects light on various points of a curved surface, and the patient indicates whether he or she sees the light.

(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 the limitations in §886.9. The 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.

§ 886.1630 AC-powered photostimulator.

(a) Identification. An AC-powered photostimulator is an AC-powered device intended to provide light stimulus which allows measurement of retinal or visual function by perceptual or electrical methods (e.g., stroboscope).

(b) Classification. Class II.