

Food and Drug Administration, HHS

§ 886.1810

system, and an alignment system intended to measure the refractive power of the eye by measuring light reflexes from the retina.

(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.

[52 FR 33355, Sept. 2, 1987, as amended at 61 FR 1124, Jan. 16, 1996; 66 FR 38812, July 25, 2001]

§ 886.1770 Manual refractor.

(a) *Identification*. A manual refractor is a device that is a set of lenses of various dioptric powers intended to measure the refractive error 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.

[52 FR 33355, Sept. 2, 1987, as amended at 53 FR 35605, Sept. 14, 1988; 66 FR 38812, July 25, 2001]

§ 886.1780 Retinoscope.

(a) *Identification*. A retinoscope is an AC-powered or battery-powered device intended to measure the refraction of the eye by illuminating the retina and noting the direction of movement of the light on the retinal surface and of the refraction by the eye of the emergent rays.

(b) *Classification*. (1) Class II (special controls) for the AC-powered device.

(2) Class I (general controls) for the battery-powered device. The class I battery-powered device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 886.9. The battery-powered device is 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 of this chapter, with respect to general requirements concerning records, and § 820.198 of this

chapter, with respect to complaint files.

[55 FR 48442, Nov. 20, 1990; 55 FR 51799, Dec. 17, 1990, as amended at 65 FR 2320, Jan. 14, 2000]

§ 886.1790 Nearpoint ruler.

(a) *Identification*. A nearpoint ruler is a device calibrated in centimeters intended to measure the nearpoint of convergence (the point to which the visual lines are directed when convergence is at its maximum).

(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.

[52 FR 33355, Sept. 2, 1987, as amended at 53 FR 35605, Sept. 14, 1988; 53 FR 40825, Oct. 18, 1988; 66 FR 38812, July 25, 2001]

§ 886.1800 Schirmer strip.

(a) *Identification*. A Schirmer strip is a device made of filter paper or similar material intended to be inserted under a patient's lower eyelid to stimulate and evaluate formation of tears.

(b) *Classification*. Class I (general controls). If the device is made of the same materials that were used in the device before May 28, 1976, 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.

[52 FR 33355, Sept. 2, 1987, as amended at 53 FR 35605, Sept. 14, 1988; 66 FR 38812, July 25, 2001]

§ 886.1810 Tangent screen (campimeter).

(a) *Identification*. A tangent screen (campimeter) is an AC-powered or battery-powered device that is a large square cloth chart with a central mark of fixation intended to map on a flat surface the central 30 degrees of a patient's visual field. This generic type of device includes projection tangent

§ 886.1840

screens, target tangent screens and targets, felt tangent screens, and stereo campimeters.

(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.

[55 FR 48442, Nov. 20, 1990, as amended at 59 FR 63013, Dec. 7, 1994; 66 FR 38812, July 25, 2001]

§ 886.1840 Simulatan (including crossed cylinder).

(a) *Identification*. A simulatan (including crossed cylinder) is a device that is a set of pairs of cylinder lenses that provides various equal plus and minus refractive strengths. The lenses are arranged so that the user can exchange the positions of plus and minus cylinder lenses of equal strengths. The device is intended for subjective refraction (refraction in which the patient judges whether a given object is clearly in focus, as the examiner uses different lenses).

(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.

[52 FR 33355, Sept. 2, 1987, as amended at 53 FR 35605, Sept. 14, 1988; 66 FR 38812, July 25, 2001]

§ 886.1850 AC-powered slitlamp bio-microscope.

(a) *Identification*. An AC-powered slitlamp biomicroscope is an AC-powered device that is a microscope in-

21 CFR Ch. I (4-1-12 Edition)

tended for use in eye examination that projects into a patient's eye through a control diaphragm a thin, intense beam of light.

(b) *Classification*. Class II.

§ 886.1860 Ophthalmic instrument stand.

(a) *Identification*. An ophthalmic instrument stand is an AC-powered or nonpowered device intended to store ophthalmic instruments in a readily accessible position.

(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.

[55 FR 48442, Nov. 20, 1990, as amended at 59 FR 63013, Dec. 7, 1994; 66 FR 38812, July 25, 2001]

§ 886.1870 Stereoscope.

(a) *Identification*. A stereoscope is an AC-powered or battery-powered device that combines the images of two similar objects to produce a three-dimensional appearance of solidity and relief. It is intended to measure the angle of strabismus (eye muscle deviation), evaluate binocular vision (usage of both eyes to see), and guide a patient's corrective exercises of eye 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