

§ 886.1790

records, and § 820.198, with respect to complaint files.

[55 FR 48442, Nov. 20, 1990; 55 FR 51799, Dec. 17, 1990]

§ 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. The device is exempt from the premarket notification procedures in part 807, subpart E of this chapter. The device also is exempt from the current good manufacturing practice regulations 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]

§ 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. 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 part 807, subpart E of this chapter.

[52 FR 33355, Sept. 2, 1987, as amended at 53 FR 35605, Sept. 14, 1988]

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

(b) *Classification.* Class I. The AC-powered device and the battery-powered device are exempt from the pre-

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market notification procedures in subpart E of part 807 of this chapter. The battery-powered device is also exempt from the current good manufacturing practice regulations 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]

§ 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. The device is exempt from the premarket notification procedures in part 807, subpart E of this chapter. The device also is exempt from the current good manufacturing practice regulations 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]

§ 886.1850 AC-powered slitlamp biomicroscope.

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