

Food and Drug Administration, HHS

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tumor masses on, around, or within the eye.

(b) *Classification.* Class II.

§ 886.1680 Ophthalmic projector.

(a) *Identification.* An ophthalmic projector is an AC-powered device intended to project an image on a screen for vision testing.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[55 FR 48442, Nov. 20, 1990, as amended at 59 FR 63013, Dec. 7, 1994]

§ 886.1690 Pupillograph.

(a) *Identification.* A pupillograph is an AC-powered device intended to measure the pupil of the eye by reflected light and record the responses of the pupil.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[55 FR 48442, Nov. 20, 1990, as amended at 59 FR 63013, Dec. 7, 1994]

§ 886.1700 Pupillometer.

(a) *Identification.* A pupillometer is an AC-powered or manual device intended to measure by reflected light the width or diameter of the pupil of the eye.

(b) *Classification.* Class I. The AC-powered device and the manual device are exempt from the premarket notification procedures in subpart E of part 807 of this chapter. The manual 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]

§ 886.1750 Skiascopic rack.

(a) *Identification.* A skiascopic rack is a device that is a rack and a set of attached ophthalmic lenses of various dioptric strengths intended as an aid in refraction.

(b) *Classification.* Class I. The device is exempt from the premarket notification

procedures in subpart E of part 807 of this chapter.

[52 FR 33355, Sept. 2, 1987, as amended at 61 FR 1124, Jan. 16, 1996]

§ 886.1760 Ophthalmic refractometer.

(a) *Identification.* An ophthalmic refractometer is an automatic AC-powered device that consists of a fixation system, a measurement and recording 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. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[52 FR 33355, Sept. 2, 1987, as amended at 61 FR 1124, Jan. 16, 1996]

§ 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. 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]

§ 886.1780 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.* Class I for the battery-powered device. Class II for the AC-powered device. The battery-powered device 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

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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.