

§ 886.1050 Adaptometer (biophotometer).

(a) *Identification.* An adaptometer (biophotometer) is an AC-powered device that provides a stimulating light source which has various controlled intensities intended to measure the time required for retinal adaptation (regeneration of the visual purple) and the minimum light threshold.

(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.

[55 FR 48441, Nov. 20, 1990, as amended at 59 FR 63012, Dec. 7, 1994; 66 FR 38809, July 25, 2001]

§ 886.1070 Anomaloscope.

(a) *Identification.* An anomaloscope is an AC-powered device intended to test for anomalies of color vision by displaying mixed spectral lines to be matched by the patient.

(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.

[55 FR 48441, Nov. 20, 1990, as amended at 59 FR 63012, Dec. 7, 1994; 66 FR 38810, July 25, 2001]

§ 886.1090 Haidinger brush.

(a) *Identification.* A Haidinger brush is an AC-powered device that provides two conical brushlike images with apexes touching which are viewed by the patient through a Nicol prism and intended to evaluate visual function. It may include a component for measuring macular integrity.

(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.

[55 FR 48441, Nov. 20, 1990, as amended at 59 FR 63012, Dec. 7, 1994; 66 FR 38810, July 25, 2001; 72 FR 17400, Apr. 9, 2007]

§ 886.1120 Ophthalmic camera.

(a) *Identification.* An ophthalmic camera is an AC-powered device intended to take photographs of the eye and the surrounding area.

(b) *Classification.* Class II.

[55 FR 48441, Nov. 20, 1990]

§ 886.1140 Ophthalmic chair.

(a) *Identification.* An ophthalmic chair is an AC-powered or manual device with adjustable positioning in which a patient is to sit or recline during ophthalmological examination or treatment.

(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, subject to the limitations in § 886.9. The manual 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 48441, Nov. 20, 1990, as amended at 59 FR 63012, Dec. 7, 1994; 66 FR 38810, July 25, 2001]

§ 886.1150 Visual acuity chart.

(a) *Identification.* A visual acuity chart is a device that is a chart, such as a Snellen chart with block letters or other symbols in graduated sizes, intended to test visual acuity.

(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 35603, Sept. 14, 1988; 53 FR 40825, Oct. 18, 1988; 66 FR 38810, July 25, 2001]

§ 886.1160 Color vision plate illuminator.

(a) *Identification.* A color vision plate illuminator is an AC-powered device that is a lamp intended to properly illuminate color vision testing plates. It may include a filter.

§ 886.1170

(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.

[55 FR 48441, Nov. 20, 1990, as amended at 59 FR 63012, Dec. 7, 1994; 66 FR 38810, July 25, 2001]

§ 886.1170 Color vision tester.

(a) *Identification*. A color vision tester is a device that consists of various colored materials, such as colored yarns or color vision plates (multicolored plates which patients with color vision deficiency would perceive as being of one color), intended to evaluate color vision.

(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 35603, Sept. 14, 1988; 66 FR 38810, July 25, 2001]

§ 886.1190 Distometer.

(a) *Identification*. A distometer is a device intended to measure the distance between the cornea and a corrective lens during refraction to help measure the change of the visual image when a lens is in place.

(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 35603, Sept. 14, 1988; 66 FR 38810, July 25, 2001]

21 CFR Ch. I (4–1–13 Edition)

§ 886.1200 Optokinetic drum.

(a) *Identification*. An optokinetic drum is a drum-like device covered with alternating white and dark stripes or pictures that can be rotated on its handle. The device is intended to elicit and evaluate nystagmus (involuntary rapid movement of the eyeball) in patients.

(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 35604, Sept. 14, 1988; 66 FR 38810, July 25, 2001]

§ 886.1220 Corneal electrode.

(a) *Identification*. A corneal electrode is an AC-powered device, usually part of a special contact lens, intended to be applied directly to the cornea to provide data showing the changes in electrical potential in the retina after electroretinography (stimulation by light).

(b) *Classification*. Class II.

§ 886.1250 Euthyscope.

(a) *Identification*. A euthyscope is a device that is a modified AC-powered or battery-powered ophthalmoscope (a perforated mirror device intended to inspect the interior of the eye) that projects a bright light encompassing an arc of about 30 degrees onto the fundus of the eye. The center of the light bundle is blocked by a black disk covering the fovea (the central depression of the macular retinae where only cones are present and blood vessels are lacking). The device is intended for use in the treatment of amblyopia (dimness of vision without apparent disease of the eye).