

§ 886.1405

§ 886.1405 Ophthalmic trial lens set.

(a) *Identification.* An ophthalmic trial lens set is a device that is a set of lenses of various dioptric powers intended to be handheld or inserted in a trial frame for vision testing to determine 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]

§ 886.1410 Ophthalmic trial lens clip.

(a) *Identification.* An ophthalmic trial lens clip is a device intended to hold prisms, spheres, cylinders, or occluders on a trial frame or spectacles for vision testing.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in part 807, subpart E of this chapter. The 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 records, and § 820.198, with respect to complaint files.

[52 FR 33355, Sept. 2, 1987, as amended at 53 FR 35604, Sept. 14, 1988]

§ 886.1415 Ophthalmic trial lens frame.

(a) *Identification.* An ophthalmic trial lens frame is a mechanical device intended to hold trial lenses for vision testing.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in part 807, subpart E of this chapter. The 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 records, and § 820.198, with respect to complaint files.

[52 FR 33355, Sept. 2, 1987, as amended at 53 FR 35604, Sept. 14, 1988]

§ 886.1420 Ophthalmic lens gauge.

(a) *Identification.* An ophthalmic lens gauge is a calibrated device intended to manually measure the curvature of a spectacle lens.

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(b) *Classification.* Class I. 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 35604, Sept. 14, 1988]

§ 886.1425 Lens measuring instrument.

(a) *Identification.* A lens measuring instrument is an AC-powered device intended to measure the power of lenses, prisms, and their centers (e.g., lensometer).

(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]

§ 886.1430 Ophthalmic contact lens radius measuring device.

(a) *Identification.* An ophthalmic contact lens radius measuring device is an AC-powered device that is a microscope and dial gauge intended to measure the radius of a contact lens.

(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]

§ 886.1435 Maxwell spot.

(a) *Identification.* A Maxwell spot is an AC-powered device that is a light source with a red and blue filter intended to test macular function.

(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]

§ 886.1450 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 penoscope or eye gauge magnifier.

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

of this chapter only when the device does not include computer software in the unit or topographers.

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

§ 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. The device is exempt from the premarket notification procedures in part 807, subpart E of this chapter. The 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 records, and § 820.198, with respect to complaint files.

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

§ 886.1500 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. The device is exempt from the premarket notification procedures in part 807, subpart E of this chapter. The 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 records, and § 820.198, with respect to complaint files.

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

§ 886.1510 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. The manual device is exempt from the premarket notification procedures in part 807, subpart E of this chapter, and it 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 the complaint files.

[55 FR 48442, Nov. 20, 1990]

§ 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.

§ 886.1640 Ophthalmic preamplifier.

(a) *Identification.* An ophthalmic preamplifier is an AC-powered or battery-powered device intended to amplify electrical signals from the eye in electroretinography (recording retinal action currents from the surface of the eyeball after stimulation by light), electrooculography (testing for retinal dysfunction by comparing the standing potential in the front and the back of the eyeball), and electromyography (recording electrical currents generated in active muscle).

(b) *Classification.* Class II.

§ 886.1650 Ophthalmic bar prism.

(a) *Identification.* An ophthalmic bar prism is a device that is a bar composed of fused prisms of gradually increasing strengths intended to measure latent and manifest strabismus (eye muscle deviation) or the power of fusion of a patient's eyes.