

§ 886.1655

(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]

§ 886.1655 Ophthalmic Fresnel prism.

(a) *Identification*. An ophthalmic Fresnel prism is a device that is a thin plastic sheet with embossed rulings which provides the optical effect of a prism. The device is intended to be applied to spectacle lenses to give a prismatic effect.

(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]

§ 886.1660 Gonioscopic prism.

(a) *Identification*. A gonioscopic prism is a device that is a prism intended to be placed on the eye to study the anterior chamber. The device may have angled mirrors to facilitate visualization of anatomical features.

(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 53 FR 35605, Sept. 14, 1988; 59 FR 63013, Dec. 7, 1994]

§ 886.1665 Ophthalmic rotary prism.

(a) *Identification*. An ophthalmic rotary prism is a device with various prismatic powers intended to be handheld and used to measure ocular deviation in patients with latent or

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manifest strabismus (eye muscle deviation).

(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]

§ 886.1670 Ophthalmic isotope uptake probe.

(a) *Identification*. An ophthalmic isotope uptake probe is an AC-powered device intended to measure, by a probe which is placed in close proximity to the eye, the uptake of a radioisotope (phosphorus 32) by tumors to detect 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.