§ 886.1680 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 (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.


§ 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 (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.


§ 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 (general controls). 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.


§ 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 dioptic strengths intended as an aid in refraction.

(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.


§ 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 (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.


§ 886.1770 Manual refractor.

(a) Identification. A manual refractor is a device that is a set of lenses of various dioptic powers intended to measure the refractive error of the eye.

(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.


§ 886.1780 Retinoscope.

(a) Identification. A retinoscope is an AC-powered or battery-powered device