

Food and Drug Administration, HHS

§ 886.1375

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]

§ 886.1330 Amsler grid.

(a) *Identification.* An Amsler grid is a device that is a series of charts with grids of different sizes that are held at 30 centimeters distance from the patient and intended to rapidly detect central and paracentral irregularities in the visual field.

(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]

§ 886.1340 Haploscope.

(a) *Identification.* A haploscope is an AC-powered device that consists of two movable viewing tubes, each containing a slide carrier, a low-intensity light source for the illumination of the slides, and a high-intensity light source for creating afterimages. The device is intended to measure strabismus (eye muscle imbalance), to assess binocular vision (use of both eyes to see), and to treat suppression and amblyopia (dimness of vision without any apparent disease 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.

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

§ 886.1350 Keratoscope.

(a) *Identification.* A keratoscope is an AC-powered or battery-powered device intended to measure and evaluate the

corneal curvature of the eye. Lines and circles within the keratoscope are used to observe the corneal reflex. This generic type of device includes the photokeratoscope which records corneal curvature by taking photographs of the cornea.

(b) The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 886.9. The battery-powered device is 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 of this chapter, with respect to general requirements concerning records, and § 820.198 of this chapter, with respect to complaint files

[55 FR 48441, Nov. 20, 1990, as amended at 59 FR 63012, Dec. 7, 1994; 65 FR 2320, Jan. 14, 2000]

§ 886.1360 Visual field laser instrument.

(a) *Identification.* A visual field laser instrument is an AC-powered device intended to provide visible laser radiation that produces an interference pattern on the retina to evaluate retinal function.

(b) *Classification.* Class II.

§ 886.1375 Bagolini lens.

(a) *Identification.* A Bagolini lens is a device that consists of a plane lens containing almost imperceptible striations that do not obscure visualization of objects. The device is placed in a trial frame and intended to determine harmonious/anomalous retinal correspondence (a condition in which corresponding points on the retina have the same directional values).

(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,

§ 886.1380

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]

§ 886.1380 Diagnostic condensing lens.

(a) *Identification.* A diagnostic condensing lens is a device used in binocular indirect ophthalmoscopy (a procedure that produces an inverted or reversed direct magnified image of the eye) intended to focus reflected light from the fundus 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.

[52 FR 33355, Sept. 2, 1987, as amended at 53 FR 35604, Sept. 14, 1988; 66 FR 38810, July 25, 2001]

§ 886.1385 Polymethylmethacrylate (PMMA) diagnostic contact lens.

(a) *Identification.* A polymethylmethacrylate (PMMA) diagnostic contact lens is a device that is a curved shell of PMMA intended to be applied for a short period of time directly on the globe or cornea of the eye for diagnosis or therapy of intraocular abnormalities.

(b) *Classification.* Class II.

§ 886.1390 Flexible diagnostic Fresnel lens.

(a) *Identification.* A flexible diagnostic Fresnel lens is a device that is a very thin lens which has its surface a concentric series of increasingly refractive zones. The device is intended to be applied to the back of the spectacle lenses of patients with aphakia (absence of the lens 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

21 CFR Ch. I (4–1–10 Edition)

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 38811, July 25, 2001]

§ 886.1395 Diagnostic Hruby fundus lens.

(a) *Identification.* A diagnostic Hruby fundus lens is a device that is a 55 diopter lens intended for use in the examination of the vitreous body and the fundus of the eye under slitlamp illumination and magnification.

(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 38811, July 25, 2001]

§ 886.1400 Maddox lens.

(a) *Identification.* A Maddox lens is a device that is a series of red cylinders that change the size, shape, and color of an image. The device is intended to be handheld or placed in a trial frame to evaluate eye muscle dysfunction.

(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,