

§ 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

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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,