Subpart F—Therapeutic Devices

§ 886.5100 Ophthalmic beta radiation source.
(a) Identification. An ophthalmic beta radiation source is a device intended to apply superficial radiation to benign and malignant ocular growths.
(b) Classification. Class II.

§ 886.5120 Low-power binocular loupe.
(a) Identification. A low-power binocular loupe is a device that consists of two eyepieces, each with a lens or lens system, intended for medical purposes to magnify the appearance of objects.
(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.

§ 886.5420 Contact lens inserter/remover.
(a) Identification. A contact lens inserter/remover is a handheld device intended to insert or remove contact lenses by surface adhesion or suction.
(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.

§ 886.5540 Low-vision magnifier.
(a) Identification. A low-vision magnifier is a device that consists of a magnifying lens intended for use by a patient who has impaired vision. The device may be held in the hand or attached to spectacles.
(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.

§ 886.5600 Ptosis crutch.
(a) Identification. A ptosis crutch is a device intended to be mounted on the spectacles of a patient who has ptosis (drooping of the upper eyelid as a result of faulty development or paralysis) to hold the upper eyelid open.
(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.

§ 886.5800 Ophthalmic bar reader.
(a) Identification. An ophthalmic bar reader is a device that consists of a magnifying lens intended for use by a patient who has impaired vision. The device is placed directly onto reading material to magnify print.
(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in
§ 886.5810 Ophthalmic prism reader.

(a) Identification. An ophthalmic prism reader is a device intended for use by a patient who is in a supine position to change the angle of print to aid reading.

(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.


§ 886.5820 Closed-circuit television reading system.

(a) Identification. A closed-circuit television reading system is a device that consists of a lens, video camera, and video monitor that is intended for use by a patient who has subnormal vision to magnify reading material.

(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.


§ 886.5840 Magnifying spectacles.

(a) Identification. Magnifying spectacles are devices that consist of spectacle frames with convex lenses intended to be worn by a patient who has impaired vision to enlarge images.

(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.


§ 886.5842 Spectacle frame.

(a) Identification. A spectacle frame is a device made of metal or plastic intended to hold prescription spectacle lenses worn by a patient to correct refractive errors.

(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.


§ 886.5844 Prescription spectacle lens.

(a) Identification. A prescription spectacle lens is a glass or plastic device that is a lens intended to be worn by a patient in a spectacle frame to provide refractive corrections in accordance with a prescription for the patient. The device may be modified to protect the eyes from bright sunlight (i.e., prescription sunglasses). Prescription sunglass lenses may be reflective, tinted, polarizing, or photosensitized.

(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.


§ 886.5850 Sunglasses (nonprescription).

(a) Identification. Sunglasses (nonprescription) are devices that consist of spectacle frames or clips with absorbing, reflective, tinted, polarizing, or photosensitized lenses intended to be worn by a person to protect the eyes from bright sunlight but not to provide refractive corrections. This device is usually available over-the-counter.