Food and Drug Administration, HHS

§ 886.5800

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 spectacle.

(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 spectacle 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