§ 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 exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in §886.9.

(b) Classification. Class I (general controls). The 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, with respect to general requirements concerning records, and §820.198, with respect to complaint files.