Food and Drug Administration, HHS

§ 886.5200 Low-power binocular loupes.

(a) Identification. A low-power binocular loupes 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 current good manufacturing practice requirements of the quality system regulation in part 820 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, 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, 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, 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, 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, subject to the limitations in § 886.9.

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.