

Food and Drug Administration, HHS

§ 892.1950

position radiographic cassettes for a radiographic exposure for medical use.

(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 § 892.9.

[53 FR 1567, Jan. 20, 1988, as amended at 61 FR 1125, Jan. 16, 1996; 66 FR 38819, July 25, 2001]

§ 892.1890 Radiographic film illuminator.

(a) *Identification.* A radiographic film illuminator is a device containing a visible light source covered with a translucent front that is intended to be used to view medical radiographs.

(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 § 892.9.

[55 FR 48444, Nov. 20, 1990, as amended at 65 FR 2323, Jan. 14, 2000]

§ 892.1900 Automatic radiographic film processor.

(a) *Identification.* An automatic radiographic film processor is a device intended to be used to develop, fix, wash, and dry automatically and continuously film exposed for medical purposes.

(b) *Classification.* Class II.

[55 FR 48444, Nov. 20, 1990]

§ 892.1910 Radiographic grid.

(a) *Identification.* A radiographic grid is a device that consists of alternating radiolucent and radiopaque strips intended to be placed between the patient and the image receptor to reduce the amount of scattered radiation reaching the image receptor.

(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 § 892.9.

[53 FR 1567, Jan. 20, 1988, as amended at 65 FR 2323, Jan. 14, 2000]

§ 892.1920 Radiographic head holder.

(a) *Identification.* A radiographic head holder is a device intended to position the patient's head during a radiographic procedure.

(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 § 892.9. 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.

[53 FR 1567, Jan. 20, 1988, as amended at 66 FR 38819, July 25, 2001]

§ 892.1940 Radiologic quality assurance instrument.

(a) *Identification.* A radiologic quality assurance instrument is a device intended for medical purposes to measure a physical characteristic associated with another radiologic device.

(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 § 892.9. 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.

[53 FR 1567, Jan. 20, 1988, as amended at 66 FR 38819, July 25, 2001]

§ 892.1950 Radiographic anthropomorphic phantom.

(a) *Identification.* A radiographic anthropomorphic phantom is a device intended for medical purposes to simulate a human body for positioning radiographic equipment.

(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 § 892.9. 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,