

§ 892.1910

(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. The device is exempt from the premarket notification procedures in subpart E of part 807. The device is exempt from the current good manufacturing practice regulations in part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 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. The device is exempt from the premarket notification procedures in subpart E of part 807. The device is exempt from the current good manufacturing practice regulations in part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 892.1950 Radiographic anthropomorphic phantom.

(a) *Identification*. A radiographic anthropomorphic phantom is a device intended for medical purposes to simu-

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late a human body for positioning radiographic equipment.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807. The device is exempt from the current good manufacturing practice regulations in part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 892.1960 Radiographic intensifying screen.

(a) *Identification*. A radiographic intensifying screen is a device that is a thin radiolucent sheet coated with a luminescent material that transforms incident x-ray photons into visible light and intended for medical purposes to expose radiographic film.

(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]

§ 892.1970 Radiographic ECG/respirator synchronizer.

(a) *Identification*. A radiographic ECG/respirator synchronizer is a device intended to be used to coordinate an x-ray film exposure with the signal from an electrocardiograph (ECG) or respirator at a predetermined phase of the cardiac or respiratory cycle.

(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]

§ 892.1980 Radiologic table.

(a) *Identification*. A radiologic table is a device intended for medical purposes to support a patient during radiologic procedures. The table may be fixed or tilting and may be electrically powered.

(b) *Classification*. Class II (special controls). The device is exempt from the premarket notification procedures