

(b) *Classification*. Class II.

**§ 892.1860 Radiographic film/cassette changer.**

(a) *Identification*. A radiographic film/cassette changer is a device intended to be used during a radiologic procedure to move a radiographic film or cassette between x-ray exposures and to position it during the exposure.

(b) *Classification*. Class II.

**§ 892.1870 Radiographic film/cassette changer programmer.**

(a) *Identification*. A radiographic film/cassette changer programmer is a device intended to be used to control the operations of a film or cassette changer during serial medical radiography.

(b) *Classification*. Class II.

**§ 892.1880 Wall-mounted radiographic cassette holder.**

(a) *Identification*. A wall-mounted radiographic cassette holder is a device that is a support intended to hold and position radiographic cassettes for a radiographic exposure for medical use.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[53 FR 1567, Jan. 20, 1988, as amended at 61 FR 1125, Jan. 16, 1996]

**§ 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.

[55 FR 48444, Nov. 20, 1990]

**§ 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.

**§ 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 simulate 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

§ 892.1960

§ 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.

**§ 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.

[55 FR 48444, Nov. 20, 1990]

**§ 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.

**§ 892.1990 Transilluminator for breast evaluation.**

(a) *Identification.* A transilluminator, also known as a diaphanoscope or lightscanner, is an electrically powered device that uses low intensity emissions of visible light and near-infrared radiation (approximately 700–1050 nanometers (nm)), transmitted through the breast, to visualize translucent tissue for the diagnosis of cancer, other conditions, diseases, or abnormalities.

(b) *Classification.* Class III (premarket approval).

(c) *Date premarket approval (PMA) or notice of completion of a product development protocol (PDP) is required.* The effective date of the requirement for premarket approval has not been established. See § 892.3.

[60 FR 36639, July 18, 1995]

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Subparts C–E [Reserved]

Subpart F—Therapeutic Devices

**§ 892.5050 Medical charged-particle radiation therapy system.**

(a) *Identification.* A medical charged-particle radiation therapy system is a device that produces by acceleration high energy charged particles (e.g., electrons and protons) intended for use in radiation therapy. This generic type of device may include signal analysis and display equipment, patient and equipment supports, treatment planning computer programs, component parts, and accessories.

(b) *Classification.* Class II.

**§ 892.5300 Medical neutron radiation therapy system.**

(a) *Identification.* A medical neutron radiation therapy system is a device intended to generate high-energy neutrons for radiation therapy. This generic type of device may include signal analysis and display equipment, patient and equipment support, treatment planning computer programs, component parts, and accessories.

(b) *Classification.* Class II.

**§ 892.5650 Manual radionuclide applicator system.**

(a) *Identification.* A manual radionuclide applicator system is a manually operated device intended to apply a radionuclide source into the body or to the surface of the body for radiation therapy. This generic type of device may include patient and equipment supports, component parts, treatment planning computer programs, and accessories.

(b) *Classification.* Class I.

**§ 892.5700 Remote controlled radionuclide applicator system.**

(a) *Identification.* A remote controlled radionuclide applicator system is an electromechanical or pneumatic device intended to enable an operator to apply, by remote control, a radionuclide source into the body or to the surface of the body for radiation therapy. This generic type of device may include patient and equipment supports, component parts, treatment