Food and Drug Administration, HHS

§ 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, 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.


(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.


§ 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 in subpart E of part 807 of this chapter subject to § 892.9.

[53 FR 1567, Jan. 20, 1988, as amended at 63 FR 59231, Nov. 3, 1998]

§ 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]

§ 892.2010 Medical image storage device.

(a) Identification. A medical image storage device is a device that provides electronic storage and retrieval functions for medical images. Examples include devices employing magnetic and optical discs, magnetic tape, and digital memory.

(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.


§ 892.2020 Medical image communications device.

(a) Identification. A medical image communications device provides electronic transfer of medical image data between medical devices. It may include a physical communications medium, modems, interfaces, and a communications protocol.

(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.


§ 892.2030 Medical image digitizer.

(a) Identification. A medical image digitizer is a device intended to convert an analog medical image into a