§ 892.1760 Diagnostic x-ray tube housing assembly.

(a) Identification. A diagnostic x-ray tube housing assembly is an x-ray generating tube enclosed in a radiation-shielded housing that is intended for diagnostic purposes. This generic type of device may include high voltage and filament transformers or other appropriate components.

(b) Classification. Class II.

§ 892.1770 Diagnostic x-ray tube mount.

(a) Identification. A diagnostic x-ray tube mount is a device intended to support and to position the diagnostic x-ray tube housing assembly for a medical 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.

§ 892.1780 Pneumoencephalographic chair.

(a) Identification. A pneumoencephalographic chair is a chair intended to support and position a patient during pneumoencephalography (x-ray imaging of the brain).

(b) Classification. Class II.

§ 892.1820 Radiologic patient cradle.

(a) Identification. A radiologic patient cradle is a support device intended to be used for rotational positioning about the longitudinal axis of a patient during radiologic procedures.

(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.

§ 892.1830 Radiographic film.

(a) Identification. Radiographic film is a device that consists of a thin sheet of radiotransparent material coated on one or both sides with a photographic emulsion intended to record images during diagnostic radiologic procedures.

(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.

§ 892.1840 Radiographic film cassette.

(a) Identification. A radiographic film cassette is a device intended for use during diagnostic x-ray procedures to hold a radiographic film in close contact with an x-ray intensifying screen and to provide a light-proof enclosure for direct exposure of radiographic film.

(b) Classification. Class I (general controls).

§ 892.1850 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.

§ 892.1860 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.

§ 892.1870 Wall-mounted radiographic cassette holder.

(a) Identification. A wall-mounted radiographic cassette holder is a device that is a support intended to hold and...
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§ 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.