
(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 II (special controls; voluntary standards—Digital Imaging and Communications in Medicine (DICOM) Std., Joint Photographic Experts Group (JPEG) Std.).

[63 FR 23387, Apr. 29, 1998]

§ 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 digital format. Examples include systems employing video frame grabbers, and scanners which use lasers or charge-coupled devices.

(b) Classification. Class II (special controls; voluntary standards—Digital Imaging and Communications in Medicine (DICOM) Std., Joint Photographic Experts Group (JPEG) Std.).

[63 FR 23387, Apr. 29, 1998]

§ 892.2040  Medical image hardcopy device.

(a) Identification. A medical image hardcopy device is a device that produces a visible printed record of a medical image and associated identification information. Examples include multifORMAT cameras and laser printers.

(b) Classification. Class II (special controls; voluntary standards—Digital Imaging and Communications in Medicine (DICOM) Std., Joint Photographic Experts Group (JPEG) Std.).