

§ 892.1100

spectroscopy, phosphorus-31 spectroscopy, and chemical shift imaging (preserving simultaneous frequency and spatial information).

(b) *Classification*. Class II.

[53 FR 5078, Feb. 1, 1989]

§ 892.1100 Scintillation (gamma) camera.

(a) *Identification*. A scintillation (gamma) camera is a device intended to image the distribution of radionuclides in the body by means of a photon radiation detector. This generic type of device may include signal analysis and display equipment, patient and equipment supports, radionuclide anatomical markers, component parts, and accessories.

(b) *Classification*. Class I.

[55 FR 48443, Nov. 20, 1990]

§ 892.1110 Positron camera.

(a) *Identification*. A positron camera is a device intended to image the distribution of positron-emitting radionuclides in the body. This generic type of device may include signal analysis and display equipment, patient and equipment supports, radionuclide anatomical markers, component parts, and accessories.

(b) *Classification*. Class I.

[55 FR 48444, Nov. 20, 1990]

§ 892.1130 Nuclear whole body counter.

(a) *Identification*. A nuclear whole body counter is a device intended to measure the amount of radionuclides in the entire body. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

(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 59 FR 63015, Dec. 7, 1994]

[55 FR 48444, Nov. 20, 1990]

§ 892.1170 Bone densitometer.

(a) *Identification*. A bone densitometer is a device intended for medical purposes to measure bone density and

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mineral content by x-ray or gamma ray transmission measurements through the bone and adjacent tissues. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

(b) *Classification*. Class II.

§ 892.1200 Emission computed tomography system.

(a) *Identification*. An emission computed tomography system is a device intended to detect the location and distribution of gamma ray- and positron-emitting radionuclides in the body and produce cross-sectional images through computer reconstruction of the data. This generic type of device may include signal analysis and display equipment, patient and equipment supports, radionuclide anatomical markers, component parts, and accessories.

(b) *Classification*. Class II.

§ 892.1220 Fluorescent scanner.

(a) *Identification*. A fluorescent scanner is a device intended to measure the induced fluorescent radiation in the body by exposing the body to certain x-rays or low-energy gamma rays. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts and accessories.

(b) *Classification*. Class II.

§ 892.1300 Nuclear rectilinear scanner.

(a) *Identification*. A nuclear rectilinear scanner is a device intended to image the distribution of radionuclides in the body by means of a detector (or detectors) whose position moves in two directions with respect to the patient. This generic type of device may include signal analysis and display equipment, patient and equipment supports, radionuclide anatomical markers, component parts, and accessories.

(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 2322, Jan. 14, 2000]