

§ 892.1180

21 CFR Ch. I (4–1–12 Edition)

§ 892.1180 Bone sonometer.

(a) *Identification.* A bone sonometer is a device that transmits ultrasound energy into the human body to measure acoustic properties of bone that indicate overall bone health and fracture risk. The primary components of the device are a voltage generator, a transmitting transducer, a receiving transducer, and hardware and software for reception and processing of the received ultrasonic signal.

(b) *Classification.* Class II (special controls). The special control for this device is FDA's "Guidance for Industry and FDA Staff; Class II Special Controls Guidance Document: Bone Sonometers." See § 892.1(e) for the availability of this guidance document.

[73 FR 40969, July 17, 2008]

§ 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 equip-

ment, 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 the limitations in § 892.9.

[55 FR 48444, Nov. 20, 1990, as amended at 65 FR 2322, Jan. 14, 2000; 66 FR 38818, July 25, 2001]

§ 892.1310 Nuclear tomography system.

(a) *Identification.* A nuclear tomography system is a device intended to detect nuclear radiation in the body and produce images of a specific cross-sectional plane of the body by blurring or eliminating detail from other planes. This generic type of devices may include signal analysis and display equipment, patient and equipment supports, radionuclide anatomical markers, component parts, and accessories.

(b) *Classification.* Class II.

§ 892.1320 Nuclear uptake probe.

(a) *Identification.* A nuclear uptake probe is a device intended to measure the amount of radionuclide taken up by a particular organ or body region. This generic type of device may include a single or multiple detector probe, signal analysis and display equipment, patient and equipment supports, 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]

§ 892.1330 Nuclear whole body scanner.

(a) *Identification.* A nuclear whole body scanner is a device intended to measure and image the distribution of radionuclides in the body by means of a wide-aperture detector whose position moves in one direction with respect to the patient. This generic type of device may include signal analysis and display equipment, patient and