

**Food and Drug Administration, HHS**

**§ 892.1380**

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 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 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]

**§ 892.1350 Nuclear scanning bed.**

(a) *Identification*. A nuclear scanning bed is an adjustable bed intended to support a patient during a nuclear medicine 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 § 892.9.

[55 FR 48444, Nov. 20, 1990, as amended at 59 FR 63015, Dec. 7, 1994; 65 FR 2322, Jan. 14, 2000]

**§ 892.1360 Radionuclide dose calibrator.**

(a) *Identification*. A radionuclide dose calibrator is a radiation detection device intended to assay radionuclides before their administration to patients.

(b) *Classification*. Class II.

**§ 892.1370 Nuclear anthropomorphic phantom.**

(a) *Identification*. A nuclear anthropomorphic phantom is a human tissue facsimile that contains a radioactive source or a cavity in which a radioactive sample can be inserted. It is intended to calibrate nuclear uptake probes or other medical instruments.

(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.

[53 FR 1567, Jan. 20, 1988, as amended at 54 FR 13832, Apr. 5, 1989; 66 FR 38818, July 25, 2001]

**§ 892.1380 Nuclear flood source phantom.**

(a) *Identification*. A nuclear flood source phantom is a device that consists of a radiolucent container filled with a uniformly distributed solution