§ 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.


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(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.


§ 892.1350 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.


§ 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.