

§ 892.1380

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 of a desired radionuclide. It is intended to calibrate a medical gamma camera-collimator system for uniformity of response.

(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 38819, July 25, 2001]

§ 892.1390 Radionuclide rebreathing system.

(a) *Identification.* A radionuclide rebreathing system is a device intended to be used to contain a gaseous or volatile radionuclide or a radionuclide-labeled aerosol and permit it to be respired by the patient during nuclear medicine ventilatory tests (testing process of exchange between the lungs and the atmosphere). This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

(b) *Classification.* Class II.

§ 892.1400 Nuclear sealed calibration source.

(a) *Identification.* A nuclear sealed calibration source is a device that consists of an encapsulated reference radionuclide intended for calibration of medical nuclear radiation detectors.

(b) *Classification.* Class I (general controls). The device is exempt from the

21 CFR Ch. I (4-1-08 Edition)

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 38819, July 25, 2001]

§ 892.1410 Nuclear electrocardiograph synchronizer.

(a) *Identification.* A nuclear electrocardiograph synchronizer is a device intended for use in nuclear radiology to relate the time of image formation to the cardiac cycle during the production of dynamic cardiac images.

(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]

§ 892.1420 Radionuclide test pattern phantom.

(a) *Identification.* A radionuclide test pattern phantom is a device that consists of an arrangement of radiopaque or radioactive material sealed in a solid pattern intended to serve as a test for a performance characteristic of a nuclear medicine imaging device.

(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 38819, July 25, 2001]

§ 892.1540 Nonfetal ultrasonic monitor.

(a) *Identification.* A nonfetal ultrasonic monitor is a device that projects a continuous high-frequency sound wave into body tissue other than a fetus to determine frequency changes (doppler shift) in the reflected wave and is intended for use in the investigation of nonfetal blood flow and other nonfetal body tissues in motion. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

(b) *Classification.* Class II.