§ 892.1000 Magnetic resonance diagnostic device.

(a) Identification. A magnetic resonance diagnostic device is intended for general diagnostic use to present images which reflect the spatial distribution and/or magnetic resonance spectra which reflect frequency and distribution of nuclei exhibiting nuclear magnetic resonance. Other physical parameters derived from the images and/or spectra may also be produced. The device includes hydrogen-1 (proton) imaging, sodium-23 imaging, hydrogen-1 spectroscopy, phosphorus-31 spectroscopy, and chemical shift imaging (preserving simultaneous frequency and spatial information).

(b) Classification. Class II.

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Subpart B—Diagnostic Devices

§ 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 (general controls).


§ 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 (general controls).


§ 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 (general controls). The device is exempt from the