Food and Drug Administration, HHS

§ 892.1320  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.

§ 892.1330  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 equipment, patient and equipment supports, radionuclide anatomical markers, component parts, and accessories.

(b) Classification. Class II (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.


§ 892.1340  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.

§ 892.1350  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...