Food and Drug Administration, HHS

§ 892.1310 Nuclear tomography system.

(a) Identification. A nuclear tomography system 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 (special 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.


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