

U.S. Food and Drug Administration



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[Revised as of April 1, 2007]
[CITE: 21CFR892.5650]



TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER H--MEDICAL DEVICES

PART 892 -- RADIOLOGY DEVICES

Subpart F--Therapeutic Devices

Sec. 892.5650 Manual radionuclide applicator system.

- (a) Identification. A manual radionuclide applicator system is a manually operated device intended to apply a radionuclide source into the body or to the surface of the body for radiation therapy. This generic type of device may include patient and equipment supports, component parts, treatment planning computer programs, 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.
- $[53 \ FR \ 1567, \ Jan. \ 20, \ 1988, \ as \ amended \ at \ 65 \ FR \ 2323, \ Jan. \ 14, \ 2000]$

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