Food and Drug Administration, HHS

Subpart E of part 807 of this chapter, subject to the limitations in §892.9.


§ 892.5840 Radiation therapy simulation system.

(a) Identification. A radiation therapy simulation system is a fluoroscopic or radiographic x-ray system intended for use in localizing the volume to be exposed during radiation therapy and confirming the position and size of the therapeutic irradiation field produced. This generic type of device may include signal analysis and display equipment, patient and equipment supports, treatment planning computer programs, component parts, and accessories.

(b) Classification. Class II.

§ 892.5900 X-ray radiation therapy system.

(a) Identification. An x-ray radiation therapy system is a device intended to produce and control x-rays used for radiation therapy. This generic type of device may include signal analysis and display equipment, patient and equipment supports, treatment planning computer programs, component parts, and accessories.

(b) Classification. Class II.

§ 892.5930 Therapeutic x-ray tube housing assembly.

(a) Identification. A therapeutic x-ray tube housing assembly is an x-ray generating tube encased in a radiation-shielded housing intended for use in radiation therapy. This generic type of device may include high-voltage and filament transformers or other appropriate components when contained in radiation-shielded housing.

(b) Classification. Class II.

Subpart G—Miscellaneous Devices

§ 892.6500 Personnel protective shield.

(a) Identification. A personnel protective shield is a device intended for medical purposes to protect the patient, the operator, or other persons from unnecessary exposure to radiation during radiologic procedures by providing an attenuating barrier to radiation. This generic type of device may include articles of clothing, furniture, and movable or stationary structures.

(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.


PART 895—BANNED DEVICES

Subpart A—General Provisions

§ 895.1 Scope.

(a) This part describes the procedures by which the Commissioner may institute proceedings to make a device intended for human use that presents substantial deception or an unreasonable and substantial risk of illness or injury a banned device.

(b) This part applies to any “device”, as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act (act) that is intended for human use.

(c) A device that is made a banned device in accordance with this part is adulterated under section 501(g) of the act. A restricted device that is banned may also be misbranded under section 502(q) of the act.

(d) Although this part does not cover devices intended for animal use, the manufacturer, distributor, importer, or any other person(s) responsible for the labeling of the device that is banned...