

§ 892.5840

§ 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.

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(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 61 FR 1125, Jan. 16, 1996; 65 FR 2323, Jan. 14, 2000]

PART 895—BANNED DEVICES

Subpart A—General Provisions

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895.101 Prosthetic hair fibers.

AUTHORITY: 21 U.S.C. 352, 360f, 360h, 360i, 371.

SOURCE: 44 FR 29221, May 18, 1979, unless otherwise noted.

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 cannot avoid the ban by relabeling the device for veterinary use. A device that has been banned from human use but that also has a valid veterinary use

may be marketed for use as a veterinary device only under the following conditions: The device shall comply with all requirements applicable to veterinary devices under the Federal Food, Drug, and Cosmetic Act and this chapter, and the label for the device shall bear the following statement: "For Veterinary Use Only. Caution: Federal law prohibits the distribution of this device for human use." A device so labeled, however, that is determined by the Food and Drug Administration to be intended for human use, will be considered to be a banned device. In determining whether such a device is intended for human use, the Food and Drug Administration will consider, among other things, the ultimate destination of the device.

§ 895.20 General.

The Commissioner may initiate a proceeding to make a device a banned device whenever the Commissioner finds, on the basis of all available data and information, that the device presents substantial deception or an unreasonable and substantial risk of illness or injury that the Commissioner determines cannot be, or has not been, corrected or eliminated by labeling or by a change in labeling, or by a change in advertising if the device is a restricted device.

[44 FR 29221, May 18, 1979, as amended at 57 FR 58405, Dec. 10, 1992]

§ 895.21 Procedures for banning a device.

(a) Before initiating a proceeding to make a device a banned device, the Commissioner shall find that the continued marketing of the device presents a substantial deception or an unreasonable and substantial risk of illness or injury.

(1) In determining whether the deception or risk of illness or injury is substantial, the Commissioner will consider whether the deception or risk posed by continued marketing of the device, or continued marketing of the device as presently labeled, is important, material, or significant in relation to the benefit to the public health from its continued marketing.

(2) In determining whether a device is deceptive, the Commissioner will con-

sider whether users of the device may be deceived or otherwise harmed by the device. The Commissioner is not required to determine that there was an intent on the part of the manufacturer, distributor, importer, or any other responsible person(s) to mislead or otherwise harm users of the device or that there exists any actual proof of deception of, or injury to, an individual.

(3) In determining whether a device presents deception or risk of illness or injury, the Commissioner will consider all available data and information, including data and information that the Commissioner may obtain under other provisions of the act, data and information that may be supplied by the manufacturer, distributor, or importer of the device under § 895.22, and data and information voluntarily submitted by any other interested persons.

(b) Before initiating a proceeding to make a device a banned device, the Commissioner of Food and Drugs (the Commissioner) may consult with the panel established under section 513 of the act that has expertise with respect to the type of device under consideration. The consultation with the panel may occur at a regular or specially scheduled panel meeting or may be accomplished by correspondence or telephone conversation with panel members. The Commissioner may request that the panel submit in writing any advice on the device under consideration. The Commissioner will record in written memoranda any oral communications with a panel or its members.

(c) If the Commissioner determines that any substantial deception or unreasonable and substantial risk of illness or injury or any unreasonable, direct, and substantial danger to the health of individuals presented by a device can be corrected or eliminated by labeling or change in labeling, or change in advertising if the device is a restricted device, the Commissioner will notify the responsible person of the required labeling or change in labeling or change in advertising in accordance with § 895.25. If such required relabeling or change in advertising is not accomplished in accordance with § 895.25, the Commissioner may initiate