Food and Drug Administration, HHS

§ 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 (including beam-limiting devices), and accessories.

(b) Classification. Class II.

§ 892.5770 Powered radiation therapy patient support assembly.

(a) Identification. A powered radiation therapy patient support assembly is an electrically powered adjustable couch intended to support a patient during radiation therapy.

(b) Classification. Class II.

§ 892.5780 Light beam patient position indicator.

(a) Identification. A light beam patient position indicator is a device that projects a beam of light (incoherent light or laser) to determine the alignment of the patient with a radiation beam. The beam of light is intended to be used during radiologic procedures to ensure proper positioning of the patient and to monitor alignment of the radiation beam with the patient’s anatomy.

(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 the limitations in § 892.9.


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(b) Classification. Class II.