§ 892.5700Remote controlled radio-
    nuclide applicator system.
    (a) Identification. A remote controlled radio-
        nuclide applicator system is an electromechanical or pneumatic device
        intended to enable an operator to apply, by remote control, a radio-
        nuclide source into the body or to the surface of the body for radiation ther-
        apy. This generic type of device may include patient and equipment sup-
        ports, component parts, treatment planning computer programs, and ac-
        cessories.
    (b) Classification. Class II.

§ 892.5710 Radiation therapy beam-
    shaping block.
    (a) Identification. A radiation therapy beam-shaping block is a device made of
        a highly attenuating material (such as lead) intended for medical purposes to
        modify the shape of a beam from a radiation therapy source.
    (b) Classification. Class II.

§ 892.5730 Radionuclide brachytherapy
    source.
    (a) Identification. A radionuclide brachytherapy source is a device that
        consists of a radionuclide which may be enclosed in a sealed container made
        of gold, titanium, stainless steel, or platinum and intended for medical pur-
        poses to be placed onto a body surface or into a body cavity or tissue as a
        source of nuclear radiation for therapy.
    (b) Classification. Class II.

§ 892.5740 Radionuclide teletherapy
    source.
    (a) Identification. A radionuclide teletherapy source is a device consisting of
        a radionuclide enclosed in a sealed container. The device is intended for radi-
        ation therapy, with the radiation source located at a distance from the patient’s body.
    (b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in

§ 892.5750 Radionuclide radiation ther-
    apy system.
    (a) Identification. A radionuclide radiation therapy system is a device inten-
        ded to permit an operator to administer gamma radiation therapy, with
        the radiation source located at a distance from the patient’s body. This ge-
        neric type of device may include signal analysis and display equipment, pa-
        tient and equipment supports, treatment planning computer programs, compo-
        nent 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 align-
        ment 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 pa-
        tient and to monitor alignment of the radiation beam with the patient’s anat-
        omy.
    (b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in

§ 892.5840 Radiation therapy simula-
    tion system.
    (a) Identification. A radiation therapy simulation system is a fluoroscopic or
        radiographic x-ray system intended for