§ 892.1600 Angiographic x-ray system.

(a) **Identification.** An angiographic x-ray system is a device intended for radiologic visualization of the heart, blood vessels, or lymphatic system during or after injection of a contrast medium. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

(b) **Classification.** Class II.

§ 892.1610 Diagnostic x-ray beam-limiting device.

(a) **Identification.** A diagnostic x-ray beam-limiting device is a device such as a collimator, a cone, or an aperture intended to restrict the dimensions of a diagnostic x-ray field by limiting the size of the primary x-ray beam.

(b) **Classification.** Class II.

§ 892.1620 Cine or spot fluorographic x-ray camera.

(a) **Identification.** A cine or spot fluorographic x-ray camera is a device intended to photograph diagnostic images produced by x-rays with an image intensifier.

(b) **Classification.** Class II.

§ 892.1630 Electrostatic x-ray imaging system.

(a) **Identification.** An electrostatic x-ray imaging system is a device intended for medical purposes that uses an electrostatic field across a semiconductive plate, a gas-filled chamber, or other similar device to convert a pattern of x-radiation into an electrostatic image and, subsequently, into a visible image. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

(b) **Classification.** Class II.

§ 892.1640 Radiographic film marking system.

(a) **Identification.** A radiographic film marking system is a device intended for medical purposes to add identification and other information onto radiographic film by means of exposure to visible light.

(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.

§ 892.1650 Image-intensified fluoroscopic x-ray system.

(a) **Identification.** An image-intensified fluoroscopic x-ray system is a device intended to visualize anatomical structures by converting a pattern of x-radiation into a visible image through electronic amplification. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

(b) **Classification.** Class II. When intended as an accessory to the device described in paragraph (a) of this section, the fluoroscopic compression device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 892.9.

§ 892.1660 Non-image-intensified fluoroscopic x-ray system.

(a) **Identification.** A non-image-intensified fluoroscopic x-ray system is a device intended to be used to visualize anatomical structures by using a fluorescent screen to convert a pattern of x-radiation into a visible image. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

(b) **Classification.** Class II.

§ 892.1670 Spot-film device.

(a) **Identification.** A spot-film device is an electromechanical component of a fluoroscopic x-ray system that is intended to be used for medical purposes to position a radiographic film cassette to obtain radiographs during fluoroscopy.

(b) **Classification.** Class II.

§ 892.1680 Stationary x-ray system.

(a) **Identification.** A stationary x-ray system is a permanently installed diagnostic system intended to generate and