

## § 892.1620

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

[48 FR 53047, Nov. 23, 1983, as amended at 84 FR 71818, Dec. 30, 2019]

### § 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.

[55 FR 48444, Nov. 20, 1990, as amended at 59 FR 63015, Dec. 7, 1994; 66 FR 38819, July 25, 2001]

### § 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, pa-

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tient and equipment supports, component parts, and accessories.

(b) *Classification.* Class II (special controls). An anthrogram tray or radiology dental tray intended for use with an image-intensified fluoroscopic x-ray system only is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 892.9. In addition, 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 the limitations in § 892.9.

[53 FR 1567, Jan. 20, 1988, as amended at 66 FR 57369, Nov. 15, 2001; 84 FR 71818, Dec. 30, 2019]

### § 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 (special 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.

[48 FR 53047, Nov. 23, 1983, as amended at 84 FR 71818, Dec. 30, 2019]

### § 892.1680 Stationary x-ray system.

(a) *Identification.* A stationary x-ray system is a permanently installed diagnostic system intended to generate and control x-rays for examination of various anatomical regions. This generic