

## § 892.1

- 892.1420 Radionuclide test pattern phantom.
- 892.1540 Nonfetal ultrasonic monitor.
- 892.1550 Ultrasonic pulsed doppler imaging system.
- 892.1560 Ultrasonic pulsed echo imaging system.
- 892.1570 Diagnostic ultrasonic transducer.
- 892.1600 Angiographic x-ray system.
- 892.1610 Diagnostic x-ray beam-limiting device.
- 892.1620 Cine or spot fluorographic x-ray camera.
- 892.1630 Electrostatic x-ray imaging system.
- 892.1640 Radiographic film marking system.
- 892.1650 Image-intensified fluoroscopic x-ray system.
- 892.1660 Non-image-intensified fluoroscopic x-ray system.
- 892.1670 Spot-film device.
- 892.1680 Stationary x-ray system.
- 892.1700 Diagnostic x-ray high voltage generator.
- 892.1710 Mammographic x-ray system.
- 892.1720 Mobile x-ray system.
- 892.1730 Photofluorographic x-ray system.
- 892.1740 Tomographic x-ray system.
- 892.1750 Computed tomography x-ray system.
- 892.1760 Diagnostic x-ray tube housing assembly.
- 892.1770 Diagnostic x-ray tube mount.
- 892.1820 Pneumoencephalographic chair.
- 892.1830 Radiologic patient cradle.
- 892.1840 Radiographic film.
- 892.1850 Radiographic film cassette.
- 892.1860 Radiographic film/cassette changer.
- 892.1870 Radiographic film/cassette changer programmer.
- 892.1880 Wall-mounted radiographic cassette holder.
- 892.1890 Radiographic film illuminator.
- 892.1900 Automatic radiographic film processor.
- 892.1910 Radiographic grid.
- 892.1920 Radiographic head holder.
- 892.1940 Radiologic quality assurance instrument.
- 892.1950 Radiographic anthropomorphic phantom.
- 892.1960 Radiographic intensifying screen.
- 892.1970 Radiographic ECG/respirator synchronizer.
- 892.1980 Radiologic table.
- 892.1990 Transilluminator for breast evaluation.
- 892.2010 Medical image storage device.
- 892.2020 Medical image communications device.
- 892.2030 Medical image digitizer.
- 892.2040 Medical image hardcopy device.
- 892.2050 Picture archiving and communications system.

### Subparts C–E [Reserved]

## 21 CFR Ch. I (4–1–10 Edition)

### Subpart F—Therapeutic Devices

- 892.5050 Medical charged-particle radiation therapy system.
- 892.5300 Medical neutron radiation therapy system.
- 892.5650 Manual radionuclide applicator system.
- 892.5700 Remote controlled radionuclide applicator system.
- 892.5710 Radiation therapy beam-shaping block.
- 892.5730 Radionuclide brachytherapy source.
- 892.5740 Radionuclide teletherapy source.
- 892.5750 Radionuclide radiation therapy system.
- 892.5770 Powered radiation therapy patient support assembly.
- 892.5780 Light beam patient position indicator.
- 892.5840 Radiation therapy simulation system.
- 892.5900 X-ray radiation therapy system.
- 892.5930 Therapeutic x-ray tube housing assembly.

### Subpart G—Miscellaneous Devices

- 892.6500 Personnel protective shield.

AUTHORITY: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

SOURCE: 53 FR 1567, Jan. 20, 1988, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to part 892 appear at 73 FR 35341, June 23, 2008.

### Subpart A—General Provisions

#### § 892.1 Scope.

(a) This part sets forth the classification of radiology devices intended for human use that are in commercial distribution.

(b) The identification of a device in a regulation in this part is not a precise description of every device that is, or will be, subject to the regulation. A manufacturer who submits a pre-market notification submission for a device under part 807 cannot show merely that the device is accurately described by the section title and identification provision of a regulation in this part but shall state why the device is substantially equivalent to other devices, as required by § 807.87.

(c) To avoid duplicative listings, a radiology device that has two or more types of uses (e.g., use both as a diagnostic device and a therapeutic device) is listed in one subpart only.

(d) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of this title 21, unless otherwise noted.

(e) Guidance documents referenced in this part are available on the Internet at <http://www.fda.gov/cdrh/guidance.html>.

[53 FR 1567, Jan. 20, 1988, as amended at 73 FR 40969, July 17, 2008]

**§ 892.3 Effective dates of requirement for premarket approval.**

A device included in this part that is classified into class III (premarket approval) shall not be commercially distributed after the date shown in the regulation classifying the device unless the manufacturer has an approval under section 515 of the act (unless an exemption has been granted under section 520(g)(2) of the act). An approval under section 515 of the act consists of FDA's issuance of an order approving an application for premarket approval (PMA) for the device or declaring completed a product development protocol (PDP) for the device.

(a) Before FDA requires that a device commercially distributed before the enactment date of the amendments, or a device that has been found substantially equivalent to such a device, has an approval under section 515 of the act, FDA must promulgate a regulation under section 515(b) of the act requiring such approval, except as provided in paragraph (b) of this section. Such a regulation under section 515(b) of the act shall not be effective during the grace period ending on the 90th day after its promulgation or on the last day of the 30th full calendar month after the regulation that classifies the device into class III is effective, whichever is later. See section 501(f)(2)(B) of the act. Accordingly, unless an effective date of the requirement for premarket approval is shown in the regulation for a device classified into class III in this part, the device may be commercially distributed without FDA's issuance of an order approving a PMA or declaring completed a PDP for the device. If FDA promulgates a regulation under section 515(b) of the act requiring premarket approval for a device, section 501(f)(1)(A) of the act applies to the device.

(b) Any new, not substantially equivalent, device introduced into commercial distribution on or after May 28, 1976, including a device formerly marketed that has been substantially altered, is classified by statute (section 513(f) of the act) into class III without any grace period and FDA must have issued an order approving a PMA or declaring completed a PDP for the device before the device is commercially distributed unless it is reclassified. If FDA knows that a device being commercially distributed may be a "new" device as defined in this section because of any new intended use or other reasons, FDA may codify the statutory classification of the device into class III for such new use. Accordingly, the regulation for such a class III device states that as of the enactment date of the amendments, May 28, 1976, the device must have an approval under section 515 of the act before commercial distribution.

**§ 892.9 Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).**

The exemption from the requirement of premarket notification (section 510(k) of the act) for a generic type of class I or II device is only to the extent that the device has existing or reasonably foreseeable characteristics of commercially distributed devices within that generic type or, in the case of in vitro diagnostic devices, only to the extent that misdiagnosis as a result of using the device would not be associated with high morbidity or mortality. Accordingly, manufacturers of any commercially distributed class I or II device for which FDA has granted an exemption from the requirement of premarket notification must still submit a premarket notification to FDA before introducing or delivering for introduction into interstate commerce for commercial distribution the device when:

(a) The device is intended for a use different from the intended use of a legally marketed device in that generic type of device; e.g., the device is intended for a different medical purpose, or the device is intended for lay use where the former intended use was by health care professionals only;