

§ 886.1

21 CFR Ch. I (4–1–98 Edition)

886.3320 Eye sphere implant.
886.3340 Extraocular orbital implant.
886.3400 Keratoprosthesis.
886.3600 Intraocular lens.
886.3800 Scleral shell.
886.3920 Eye valve implant.

886.5928 Soft (hydrophilic) contact lens care products.
886.5933 [Reserved]

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

SOURCE: 52 FR 33355, Sept. 2, 1987, unless otherwise noted.

Subpart E—Surgical Devices

886.4070 Powered corneal burr.
886.4100 Radiofrequency electrosurgical cautery apparatus.
886.4115 Thermal cautery unit.
886.4150 Vitreous aspiration and cutting instrument.
886.4170 Cryophthalmic unit.
886.4230 Ophthalmic knife test drum.
886.4250 Ophthalmic electrolysis unit.
886.4270 Intraocular gas.
886.4275 Intraocular fluid.
886.4280 Intraocular pressure measuring device.
886.4300 Intraocular lens guide.
886.4335 Operating headlamp.
886.4350 Manual ophthalmic surgical instrument.
886.4360 Ocular surgery irrigation device.
886.4370 Keratome.
886.4390 Ophthalmic laser.
886.4392 Nd:YAG laser for posterior capsulotomy.
886.4400 Electronic metal locator.
886.4440 AC-powered magnet.
886.4445 Permanent magnet.
886.4570 Ophthalmic surgical marker.
886.4610 Ocular pressure applicator.
886.4670 Phacofragmentation system.
886.4690 Ophthalmic photocoagulator.
886.4750 Ophthalmic eye shield.
886.4770 Ophthalmic operating spectacles (loupes).
886.4790 Ophthalmic sponge.
886.4855 Ophthalmic instrument table.

Subpart F—Therapeutic Devices

886.5100 Ophthalmic beta radiation source.
886.5120 Low-power binocular loupe.
886.5420 Contact lens inserter/remover.
886.5540 Low-vision magnifier.
886.5600 Ptosis crutch.
886.5800 Ophthalmic bar reader.
886.5810 Ophthalmic prism reader.
886.5820 Closed-circuit television reading system.
886.5840 Magnifying spectacles.
886.5842 Spectacle frame.
886.5844 Prescription spectacle lens.
886.5850 Sunglasses (nonprescription).
886.5870 Low-vision telescope.
886.5900 Electronic vision aid.
886.5910 Image intensification vision aid.
886.5915 Optical vision aid.
886.5916 Rigid gas permeable contact lens.
886.5918 Rigid gas permeable contact lens care products.
886.5925 Soft (hydrophilic) contact lens.

Subpart A—General Provisions

§ 886.1 Scope.

(a) This part sets forth the classification of ophthalmic 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 premarket 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, an ophthalmic device that has two or more types of uses (e.g., used both as a diagnostic device and as 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 title 21 unless otherwise noted.

§ 886.3 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 paragraphs (b) and (c) 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.

(c) A device identified in a regulation in this part that is classified into class III and that is subject to the transitional provisions of section 520(1) of the act is automatically classified by statute into class III and must have an ap-

proval under section 515 of the act before being commercially distributed. Accordingly, the regulation for such a class III transitional 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.

§ 886.9 Limitations of exemptions from section 510(k) of the act.

FDA's decision to grant an exemption from the requirement of premarket notification (section 510(k) of the act) for a generic type of class I device is based upon the existing and reasonably foreseeable characteristics of commercially distributed devices within that generic type. Because FDA cannot anticipate every change in intended use or characteristic that could significantly affect a device's safety or effectiveness, manufacturers of any commercially distributed class I 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 its intended use before May 28, 1976, or the device is intended for a use different from the intended use of a preamendments device to which it had been determined to be substantially equivalent; 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; or

(b) The modified device operates using a different fundamental scientific technology than that in use in the device before May 28, 1976; e.g., a surgical instrument cuts tissue with a laser beam rather than with a sharpened metal blade, or an in vitro diagnostic device detects or identifies infectious agents by using a deoxyribonucleic acid (DNA) probe or nucleic acid hybridization technology rather than culture or immunoassay technology.

[53 FR 35603, Sept. 14, 1988]