§ 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 approval 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 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;

(b) The modified device operates using a different fundamental scientific technology than a legally marketed device in that generic type of device; 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 deoxyribonucleic acid (DNA) probe or nucleic acid hybridization technology rather than culture or immunoassay technology; or

(c) The device is an in vitro device that is intended:

1. For use in the diagnosis, monitoring, or screening of neoplastic diseases with the exception of immunohistochemical devices;

2. For use in screening or diagnosis of familial or acquired genetic disorders, including inborn errors of metabolism;

3. For measuring an analyte that serves as a surrogate marker for screening, diagnosis, or monitoring life-threatening diseases such as acquired immune deficiency syndrome (AIDS), chronic or active hepatitis, tuberculosis, or myocardial infarction or to monitor therapy;

4. For assessing the risk of cardiovascular diseases;

5. For use in diabetes management;

6. For identifying or inferring the identity of a microorganism directly from clinical material;

7. For detection of antibodies to microorganisms other than immunoglobulin G (IgG) or IgG assays
§ 886.1040 Ocular esthesiometer.

(a) Identification. An ocular esthesiometer is a device, such as a single-hair brush, intended to touch the cornea to assess corneal sensitivity.

(b) Classification. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.


§ 886.1050 Adaptometer (biophotometer).

(a) Identification. An adaptometer (biophotometer) is an AC-powered device that provides a stimulating light source which has various controlled intensities intended to measure the time required for retinal adaptation (regeneration of the visual purple) and the minimum light threshold.

(b) Classification. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.


§ 886.1070 Anomaloscope.

(a) Identification. An anomaloscope is an AC-powered device intended to test for anomalies of color vision by displaying mixed spectral lines to be matched by the patient.

(b) Classification. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.


§ 886.1090 Haidlinger brush.

(a) Identification. A Haidlinger brush is an AC-powered device that provides two conical brushlike images with apexes touching which are viewed by the patient through a Nicol prism and intended to evaluate visual function. It may include a component for measuring macular integrity.

(b) Classification. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.


§ 886.1120 Ophthalmic camera.

(a) Identification. An ophthalmic camera is an AC-powered device intended to take photographs of the eye and the surrounding area.

(b) Classification. Class II.

[55 FR 48441, Nov. 20, 1990]

§ 886.1140 Ophthalmic chair.

(a) Identification. An ophthalmic chair is an AC-powered or manual device with adjustable positioning in which a patient is to sit or recline during ophthalmological examination or treatment.

(b) Classification. Class I. The AC-powered device and the manual device are exempt from the premarket notification procedures in subpart E of part 807 of this chapter. The manual device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of §820.180, with respect to general requirements concerning records, and §820.198, with respect to complaint files.


§ 886.1150 Visual acuity chart.

(a) Identification. A visual acuity chart is a device that is a chart, such as a Snellen chart with block letters or other symbols in graduated sizes, intended to test visual acuity.

(b) Classification. Class I. The device is exempt from the premarket notification procedures in part 807, subpart E of this chapter. The device is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of §820.180, with respect to general requirements concerning records, and §820.198, with respect to complaint files.