§ 884.6195 Assisted Reproduction Embryo Image Assessment System.

(a) Identification. An Assisted Reproduction Embryo Image Assessment System is a prescription device that is designed to obtain and analyze light microscopy images of developing embryos. This device provides information to aid in the selection of embryo(s) for transfer when there are multiple embryos deemed suitable for transfer or freezing.

(b) Classification. Class II (special controls). The special control(s) for this device are:

1. Clinical performance testing must demonstrate a reasonable assurance of safety and effectiveness of the device to predict embryo development. Classification performance (sensitivity and specificity) and predictive accuracy (Positive Predictive Value and Negative Predictive Value) must be assessed at the subject and embryo levels.

2. Software validation, verification, and hazard analysis must be provided.

3. Non-clinical performance testing data must demonstrate the performance characteristics of the device. Testing must include the following:
   i. Total light exposure and output testing;
   ii. A safety analysis must be performed based on maximum (worst-case) light exposure to embryos, which also includes the safety of the light wavelength(s) emitted by the device;
   iii. Simulated-use testing;
   iv. Mouse Embryo Assay testing to assess whether device operation impacts growth and development of mouse embryos to the blastocyst stage; and
   v. Cleaning and disinfection validation of reusable components;

4. Labeling must include the following:
   i. A detailed summary of clinical performance testing, including any adverse events;
   ii. Specific instructions, warnings, precautions, and training needed for safe use of the device;
   iii. Appropriate electromagnetic compatibility information;
   iv. Validated methods and instructions for cleaning and disinfection of reusable components; and
   v. Information identifying compatible cultureware and explain how they are used with the device.

§ 884.6200 Assisted reproduction laser system.

(a) Identification. The assisted reproduction laser system is a device that images, targets, and controls the power and pulse duration of a laser beam used to ablate a small tangential hole in, or to thin, the zona pellucida of an embryo for assisted hatching or other assisted reproduction procedures.

(b) Classification. Class II (special controls). The special control is FDA’s guidance document entitled “Class II Special Controls Guidance Document: Assisted Reproduction Laser Systems.” See §884.1(e) for the availability of this guidance document.
<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>886.1170</td>
<td>Color vision tester.</td>
</tr>
<tr>
<td>886.1190</td>
<td>Distometer.</td>
</tr>
<tr>
<td>886.1200</td>
<td>Optokinetic drum.</td>
</tr>
<tr>
<td>886.1220</td>
<td>Corneal electrode.</td>
</tr>
<tr>
<td>886.1250</td>
<td>Euthyscope.</td>
</tr>
<tr>
<td>886.1270</td>
<td>Exophthalmometer.</td>
</tr>
<tr>
<td>886.1290</td>
<td>Fixation device.</td>
</tr>
<tr>
<td>886.1300</td>
<td>Afterimage flasher.</td>
</tr>
<tr>
<td>886.1320</td>
<td>Fornixscope.</td>
</tr>
<tr>
<td>886.1330</td>
<td>Amsler grid.</td>
</tr>
<tr>
<td>886.1340</td>
<td>Haploscope.</td>
</tr>
<tr>
<td>886.1350</td>
<td>Keratoscope.</td>
</tr>
<tr>
<td>886.1360</td>
<td>Visual field laser instrument.</td>
</tr>
<tr>
<td>886.1375</td>
<td>Bagolini lens.</td>
</tr>
<tr>
<td>886.1380</td>
<td>Diagnostic condensing lens.</td>
</tr>
<tr>
<td>886.1385</td>
<td>Polymethylmethacrylate (PMMA) diagnostic contact lens.</td>
</tr>
<tr>
<td>886.1390</td>
<td>Flexible diagnostic Fresnel lens.</td>
</tr>
<tr>
<td>886.1400</td>
<td>Diagnostic Hruby fundus lens.</td>
</tr>
<tr>
<td>886.1410</td>
<td>Ophthalmic trial lens set.</td>
</tr>
<tr>
<td>886.1415</td>
<td>Ophthalmic trial lens clip.</td>
</tr>
<tr>
<td>886.1420</td>
<td>Ophthalmic lens gauge.</td>
</tr>
<tr>
<td>886.1425</td>
<td>Lens measuring instrument.</td>
</tr>
<tr>
<td>886.1430</td>
<td>Ophthalmic contact lens radius measuring device.</td>
</tr>
<tr>
<td>886.1435</td>
<td>Maxwell spot.</td>
</tr>
<tr>
<td>886.1450</td>
<td>Corneal radius measuring device.</td>
</tr>
<tr>
<td>886.1460</td>
<td>Stereopsis measuring instrument.</td>
</tr>
<tr>
<td>886.1500</td>
<td>Headband mirror.</td>
</tr>
<tr>
<td>886.1510</td>
<td>Eye movement monitor.</td>
</tr>
<tr>
<td>886.1570</td>
<td>Ophthalmoscope.</td>
</tr>
<tr>
<td>886.1605</td>
<td>Perimeter.</td>
</tr>
<tr>
<td>886.1630</td>
<td>AC-powered photostimulator.</td>
</tr>
<tr>
<td>886.1640</td>
<td>Ophthalmic preamplifier.</td>
</tr>
<tr>
<td>886.1650</td>
<td>Ophthalmic bar prism.</td>
</tr>
<tr>
<td>886.1655</td>
<td>Ophthalmic Fresnel prism.</td>
</tr>
<tr>
<td>886.1660</td>
<td>Gonioscopic prism.</td>
</tr>
<tr>
<td>886.1665</td>
<td>Ophthalmic rotary prism.</td>
</tr>
<tr>
<td>886.1670</td>
<td>Ophthalmic isotope uptake probe.</td>
</tr>
<tr>
<td>886.1680</td>
<td>Ophthalmic projector.</td>
</tr>
<tr>
<td>886.1690</td>
<td>Pupillograph.</td>
</tr>
<tr>
<td>886.1700</td>
<td>Pupilometer.</td>
</tr>
<tr>
<td>886.1750</td>
<td>Skiascopic rack.</td>
</tr>
<tr>
<td>886.1760</td>
<td>Ophthalmic refractometer.</td>
</tr>
<tr>
<td>886.1770</td>
<td>Manual refractor.</td>
</tr>
<tr>
<td>886.1790</td>
<td>Retinoscope.</td>
</tr>
<tr>
<td>886.1790</td>
<td>Nearpoint ruler.</td>
</tr>
<tr>
<td>886.1800</td>
<td>Schirmer strip.</td>
</tr>
<tr>
<td>886.1810</td>
<td>Tangent screen (campimeter).</td>
</tr>
<tr>
<td>886.1840</td>
<td>Simulatan (including crossed cylinder).</td>
</tr>
<tr>
<td>886.1850</td>
<td>AC-powered slitlamp biomicroscope.</td>
</tr>
<tr>
<td>886.1860</td>
<td>Ophthalmic instrument stand.</td>
</tr>
<tr>
<td>886.1870</td>
<td>Stereoscope.</td>
</tr>
<tr>
<td>886.1880</td>
<td>Fusion and stereoscopic target.</td>
</tr>
<tr>
<td>886.1905</td>
<td>Nystagmus tape.</td>
</tr>
<tr>
<td>886.1910</td>
<td>Spectacle dissociation test system.</td>
</tr>
<tr>
<td>886.1930</td>
<td>Tonometer and accessories.</td>
</tr>
<tr>
<td>886.1940</td>
<td>Tonometer sterilizer.</td>
</tr>
<tr>
<td>886.1945</td>
<td>Transilluminator.</td>
</tr>
</tbody>
</table>

Subpart C [Reserved]
886.5844 Prescription spectacle lens.
886.5850 Sunglasses (nonprescription).
886.5870 Low-vision telescope.
886.5900 Image intensification vision aid.
886.5910 Optical vision aid.
886.5915 Rigid gas permeable contact lens.
886.5918 Rigid gas permeable contact lens care products.
886.5925 Soft (hydrophilic) contact lens.
886.5928 Soft (hydrophilic) contact lens care products.
886.5933 [Reserved]


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

EDITORIAL NOTE: Nomenclature changes to part 886 appear at 73 FR 35341, June 23, 2008.

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.

(e) Guidance documents referenced in this part are available on the Internet at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.

§ 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 when the results are not qualitative, or are used to determine immunity, or the assay is intended for use in matrices other than serum or plasma;

(8) For noninvasive testing as defined in §812.3(k) of this chapter; and

(9) For near patient testing (point of care).

[65 FR 2320, Jan. 14, 2000]
Subpart B—Diagnostic Devices

§ 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 (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 § 886.9.


§ 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 (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 § 886.9.


§ 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 (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 § 886.9.


§ 886.1090 Haidinger brush.

(a) Identification. A Haidinger 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 (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 § 886.9.


§ 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, subject to the limitations in § 886.9. The manual device is also exempt from the current good manufacturing practice requirements of the quality system regulation 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 (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 § 886.9. The device is also exempt from the current good manufacturing practice requirements of the quality system regulation.
§ 886.1160 Color vision plate illuminator.

(a) Identification. A color vision plate illuminator is an AC-powered device that is a lamp intended to properly illuminate color vision testing plates. It may include a filter.

(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 §886.9.

§ 886.1170 Color vision tester.

(a) Identification. A color vision tester is a device that consists of various colored materials, such as colored yarns or color vision plates (multicolored plates which patients with color vision deficiency would perceive as being of one color), intended to evaluate color vision.

(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 §886.9. The device is also exempt from the current good manufacturing practice requirements of the quality system regulation 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.

§ 886.1200 Optokinetic drum.

(a) Identification. An optokinetic drum is a drum-like device covered with alternating white and dark stripes or pictures that can be rotated on its handle. The device is intended to elicit and evaluate nystagmus (involuntary rapid movement of the eyeball) in patients.

(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 §886.9. The device is also exempt from the current good manufacturing practice requirements of the quality system regulation 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.

§ 886.1220 Corneal electrode.

(a) Identification. A corneal electrode is an AC-powered device, usually part of a special contact lens, intended to be applied directly to the cornea to provide data showing the changes in electrical potential in the retina after electroretinography (stimulation by light).

(b) Classification. Class II.

§ 886.1250 Euthyscope.

(a) Identification. A euthyscope is a device that is a modified AC-powered or battery-powered ophthalmoscope (a
perforated mirror device intended to inspect the interior of the eye that projects a bright light encompassing an arc of about 30 degrees onto the fundus of the eye. The center of the light bundle is blocked by a black disk covering the fovea (the central depression of the macular retinas where only cones are present and blood vessels are lacking). The device is intended for use in the treatment of amblyopia (dimness of vision without apparent disease of the eye).

(b) Classification. Class I for the battery powered device. The battery powered device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in §886.9. Class II for the AC-powered device.


§ 886.1270 Exophthalmometer.

(a) Identification. An exophthalmometer is a device, such as a ruler, gauge, or caliper, intended to measure the degree of exophthalmos (abnormal protrusion of the eyeball).

(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 §886.9.


§ 886.1290 Fixation device.

(a) Identification. A fixation device is an AC-powered device intended for use as a fixation target for the patient during ophthalmological examination. The patient directs his or her gaze so that the visual image of the object falls on the fovea centralis (the center of the macular retina of the eye.)

(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 §886.9.


§ 886.1300 Afterimage flasher.

(a) Identification. An afterimage flasher is an AC-powered light that automatically switches on and off to allow performance of an afterimage test in which the patient indicates the positions of afterimages after the light is off. The device is intended to determine harmonious/anomalous retinal correspondence (the condition in which corresponding points on the retina have the same directional value).

(b) Classification. Class II.

[55 FR 48441, Nov. 20, 1990]

§ 886.1320 Fornixscope.

(a) Identification. A fornixscope is a device intended to pull back and hold open the eyelid to aid examination of the conjunctiva.

(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 §886.9. The device is also exempt from the current good manufacturing practice requirements of the quality system regulation 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.


§ 886.1330 Amsler grid.

(a) Identification. An Amsler grid is a device that is a series of charts with grids of different sizes that are held at 30 centimeters distance from the patient and intended to rapidly detect central and paracentral irregularities in the visual field.

(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 §886.9. The device is also exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of §820.180, with respect to general requirements concerning records,
§ 886.1340 Haploscope.
(a) Identification. A haploscope is an AC-powered device that consists of two movable viewing tubes, each containing a slide carrier, a low-intensity light source for the illumination of the slides, and a high-intensity light source for creating afterimages. The device is intended to measure strabismus (eye muscle imbalance), to assess binocular vision (use of both eyes to see), and to treat suppression and amblyopia (dimness of vision without any apparent disease of the eye).
(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 §886.9.


§ 886.1350 Keratoscope.
(a) Identification. A keratoscope is an AC-powered or battery-powered device intended to measure and evaluate the corneal curvature of the eye. Lines and circles within the keratoscope are used to observe the corneal reflex. This generic type of device includes the photokeratoscope which records corneal curvature by taking photographs of the cornea.
(b) The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to §886.9. The battery-powered device is exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of §820.180 of this chapter, with respect to general requirements concerning records, and §820.198, with respect to complaint files.


§ 886.1360 Visual field laser instrument.
(a) Identification. A visual field laser instrument is an AC-powered device intended to provide visible laser radiation that produces an interference pattern on the retina to evaluate retinal function.
(b) Classification. Class II.

§ 886.1375 Bagolini lens.
(a) Identification. A Bagolini lens is a device that consists of a plane lens containing almost imperceptible striations that do not obscure visualization of objects. The device is placed in a trial frame and intended to determine harmonious/anomalous retinal correspondence (a condition in which corresponding points on the retina have the same directional values).
(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 §886.9. The device is also exempt from the current good manufacturing practice requirements of the quality system regulation 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.


§ 886.1380 Diagnostic condensing lens.
(a) Identification. A diagnostic condensing lens is a device used in binocular indirect ophthalmoscopy (a procedure that produces an inverted or reversed direct magnified image of the eye) intended to focus reflected light from the fundus of the eye.
(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 §886.9. The device is also exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of §820.180, with respect to general requirements concerning records,
§ 886.1385 Polymethylmethacrylate (PMMA) diagnostic contact lens.

(a) Identification. A polymethylmethacrylate (PMMA) diagnostic contact lens is a device that is a curved shell of PMMA intended to be applied for a short period of time directly on the globe or cornea of the eye for diagnosis or therapy of intraocular abnormalities.

(b) Classification. Class II.

§ 886.1390 Flexible diagnostic Fresnel lens.

(a) Identification. A flexible diagnostic Fresnel lens is a device that is a very thin lens which has its surface a concentric series of increasingly refractive zones. The device is intended to be applied to the back of the spectacle lenses of patients with aphakia (absence of the lens of the eye).

(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 §886.9. The device is also exempt from the current good manufacturing practice requirements of the quality system regulation 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.

§ 886.1395 Diagnostic Hruby fundus lens.

(a) Identification. A diagnostic Hruby fundus lens is a device that is a 55 diopter lens intended for use in the examination of the vitreous body and the fundus of the eye under slitlamp illumination and magnification.

(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 §886.9. The device is also exempt from the current good manufacturing practice requirements of the quality system regulation 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.

21 CFR Ch. I (4–1–16 Edition)
§ 886.1415 Ophthalmic trial lens frame.

(a) Identification. An ophthalmic trial lens frame is a mechanical device intended to hold trial lenses for vision testing.

(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 § 886.9.

§ 886.1420 Ophthalmic lens gauge.

(a) Identification. An ophthalmic lens gauge is a calibrated device intended to manually measure the curvature of a spectacle lens.

(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 § 886.9.

§ 886.1425 Lens measuring instrument.

(a) Identification. A lens measuring instrument is an AC-powered device intended to measure the power of lenses, prisms, and their centers (e.g., lensometer).

(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 § 886.9.
§ 886.1460 Stereopsis measuring instrument.

(a) Identification. A stereopsis measuring instrument is a device intended to measure depth perception by illumination of objects placed on different planes.

(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 §886.9. The device is also exempt from the current good manufacturing practice requirements of the quality system regulation 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.


§ 886.1500 Headband mirror.

(a) Identification. A headband mirror is a device intended to be strapped to the head of the user to reflect light for use in examination of the eye.

(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 §886.9. The device is also exempt from the current good manufacturing practice requirements of the quality system regulation 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.


§ 886.1510 Eye movement monitor.

(a) Identification. An eye movement monitor is an AC-powered device intended to measure and record ocular movements.

(b) Classification. Class II.

§ 886.1570 Ophthalmoscope.

(a) Identification. An ophthalmoscope is an AC-powered or battery-powered device containing illumination and viewing optics intended to examine the media (cornea, aqueous, lens, and vitreous) and the retina of the eye.

(b) Classification. Class II.

§ 886.1605 Perimeter.

(a) Identification. A perimeter is an AC-powered or manual device intended to determine the extent of the peripheral visual field of a patient. The device projects light on various points of a curved surface, and the patient indicates whether he or she sees the 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 §886.9. The device is also exempt from the current good manufacturing practice requirements of the quality system regulation 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.


§ 886.1630 AC-powered photostimulator.

(a) Identification. An AC-powered photostimulator is an AC-powered device intended to provide light stimulus which allows measurement of retinal or visual function by perceptual or electrical methods (e.g., stroboscope).

(b) Classification. Class II.

§ 886.1640 Ophthalmic preamplifier.

(a) Identification. An ophthalmic preamplifier is an AC-powered or battery-powered device intended to amplify electrical signals from the eye in electroretinography (recording retinal action currents from the surface of the eyeball after stimulation by light), electrooculography (testing for retinal dysfunction by comparing the standing potential in the front and the back of the eyeball), and electromyography (recording electrical currents generated in active muscle).

(b) Classification. Class II.

§ 886.1650 Ophthalmic bar prism.

(a) Identification. An ophthalmic bar prism is a device that is a bar composed of fused prisms of gradually increasing strengths intended to measure
Food and Drug Administration, HHS

§ 886.1680 Ophthalmic projector.

(a) Identification. An ophthalmic projector is an AC-powered device intended to project an image on a screen for vision testing.

(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 §886.9.


§ 886.1685 Ophthalmic rotary prism.

(a) Identification. An ophthalmic rotary prism is a device with various prismatic powers intended to be handheld and used to measure ocular deviation in patients with latent or manifest strabismus (eye muscle deviation).

(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 §886.9. The device is also exempt from the current good manufacturing practice requirements of the quality system regulation 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.


§ 886.1670 Ophthalmic isotope uptake probe.

(a) Identification. An ophthalmic isotope uptake probe is an AC-powered device intended to measure, by a probe which is placed in close proximity to the eye, the uptake of a radioisotope (phosphorus 32) by tumors to detect tumor masses on, around, or within the eye.

(b) Classification. Class II.

§ 886.1660 Ophthalmic Fresnel prism.

(a) Identification. An ophthalmic Fresnel prism is a device that is a thin plastic sheet with embossed rulings which provides the optical effect of a prism. The device is intended to be applied to spectacle lenses to give a prismatic effect.

(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 §886.9. The device is also exempt from the current good manufacturing practice requirements of the quality system regulation 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.


§ 886.1655 Gonioscopic prism.

(a) Identification. A gonioscopic prism is a device that is a prism intended to be placed on the eye to study the anterior chamber. The device may have angled mirrors to facilitate visualization of anatomical features.

(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 §886.9.

§ 886.1690 Pupillograph.

(a) Identification. A pupillograph is an AC-powered device intended to measure the pupil of the eye by reflected light and record the responses of the pupil.

(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 §886.9.


§ 886.1700 Pupillometer.

(a) Identification. A pupillometer is an AC-powered or manual device intended to measure by reflected light the width or diameter of the pupil of the eye.

(b) Classification. Class I (general controls). The AC-powered device and the manual device are exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in §886.9. The manual device is also exempt from the current good manufacturing practice requirements of the quality system regulation 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.


§ 886.1750 Skiascopic rack.

(a) Identification. A skiascopic rack is a device that is a rack and a set of attached ophthalmic lenses of various dioptic strengths intended as an aid in refraction.

(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 §886.9.


§ 886.1760 Ophthalmic refractometer.

(a) Identification. An ophthalmic refractometer is an automatic AC-powered device that consists of a fixation system, a measurement and recording system, and an alignment system intended to measure the refractive power of the eye by measuring light reflexes from the retina.

(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 §886.9.


§ 886.1770 Manual refractor.

(a) Identification. A manual refractor is a device that is a set of lenses of various dioptic powers intended to measure the refractive power of the eye.

(b) Classification. Class I (general controls). The device is exempt from the current good manufacturing practice requirements of the quality system regulation 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.


§ 886.1780 Retinoscope.

(a) Identification. A retinoscope is an AC-powered or battery-powered device intended to measure the refraction of the eye by illuminating the retina and noting the direction of movement of the light on the retinal surface and of the refraction by the eye of the emergent rays.

(b) Classification. (1) Class II (special controls) for the AC-powered device.

(2) Class I (general controls) for the battery-powered device. The class I battery-powered device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to §886.9. The battery-powered device is exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of §820.180 of this chapter, with respect to general requirements concerning records, and §820.198 of this chapter.
§ 886.1790 Nearpoint ruler.

(a) Identification. A nearpoint ruler is a device calibrated in centimeters intended to measure the nearpoint of convergence (the point to which the visual lines are directed when convergence is at its maximum).

(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 §886.9. The device is also exempt from the current good manufacturing practice requirements of the quality system regulation 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.


§ 886.1800 Schirmer strip.

(a) Identification. A Schirmer strip is a device made of filter paper or similar material intended to be inserted under a patient’s lower eyelid to stimulate and evaluate formation of tears.

(b) Classification. Class I (general controls). If the device is made of the same materials that were used in the device before May 28, 1976, the device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in §886.9. The device is also exempt from the current good manufacturing practice requirements of the quality system regulation 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.


§ 886.1810 Tangent screen (campimeter).

(a) Identification. A tangent screen (campimeter) is an AC-powered or battery-powered device that is a large square cloth chart with a central mark of fixation intended to map on a flat surface the central 30 degrees of a patient’s visual field. This generic type of device includes projection tangent screens, target tangent screens and targets, felt tangent screens, and stereo campimeters.

(b) Classification. Class I (general controls). The AC-powered device and the battery-powered device are exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in §886.9. The battery-powered device is also exempt from the current good manufacturing practice requirements of the quality system regulation 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.


§ 886.1840 Simulatan (including crossed cylinder).

(a) Identification. A simulatan (including crossed cylinder) is a device that is a set of pairs of cylinder lenses that provides various equal plus and minus refractive strengths. The lenses are arranged so that the user can exchange the positions of plus and minus cylinder lenses of equal strengths. The device is intended for subjective refraction (refraction in which the patient judges whether a given object is clearly in focus, as the examiner uses different lenses).

(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 §886.9. The device is also exempt from the current good manufacturing practice requirements of the quality system regulation 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.

§ 886.1850 AC-powered slitlamp biomicroscope.

(a) Identification. An AC-powered slitlamp biomicroscope is an AC-powered device that is a microscope intended for use in eye examination that projects into a patient’s eye through a control diaphragm a thin, intense beam of light.

(b) Classification. Class II.

§ 886.1860 Ophthalmic instrument stand.

(a) Identification. An ophthalmic instrument stand is an AC-powered or nonpowered device intended to store ophthalmic instruments in a readily accessible position.

(b) Classification. Class I (general controls). The AC-powered device and the battery-powered device are exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in §886.9. The battery-powered device is also exempt from the current good manufacturing practice requirements of the quality system regulation 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.


§ 886.1870 Stereoscope.

(a) Identification. A stereoscope is an AC-powered or battery-powered device that combines the images of two similar objects to produce a three-dimensional appearance of solidity and relief. It is intended to measure the angle of strabismus (eye muscle deviation), evaluate binocular vision (usage of both eyes to see), and guide a patient’s corrective exercises of eye muscles.

(b) Classification. Class I (general controls). The AC-powered device and the battery-powered device are exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in §886.9. The battery-powered device is also exempt from the current good manufacturing practice requirements of the quality system regulation 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.


§ 886.1880 Fusion and stereoscopic target.

(a) Identification. A fusion and stereoscopic target is a device intended for use as a viewing object with a stereoscope (§886.1870).

(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 §886.9. The device is also exempt from the current good manufacturing practice requirements of the quality system regulation 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.


§ 886.1905 Nystagmus tape.

(a) Identification. Nystagmus tape is a device that is a long, narrow strip of fabric or other flexible material on which a series of objects are printed. The device is intended to be moved across a patient’s field of vision to elicit optokinetic nystagmus (abnormal and irregular eye movements) and to test for blindness.

(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 §886.9. The device is also exempt from the current good manufacturing practice requirements of the quality system regulation 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.

§ 886.1910 Spectacle dissociation test system.
(a) Identification. A spectacle dissociation test system is an AC-powered or battery-powered device, such as a Lancaster test system, that consists of a light source and various filters, usually red or green filters, intended to subjectively measure imbalance of ocular muscles.
(b) Classification. Class I (general controls). The AC-powered device and the battery-powered device are exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in §886.9. The battery-powered device is also exempt from the current good manufacturing practice requirements of the quality system regulation 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.


§ 886.1930 Tonometer and accessories.
(a) Identification. A tonometer and accessories is a manual device intended to measure intraocular pressure by applying a known force on the globe of the eye and measuring the amount of indentation produced (Schiotz type) or to measure intraocular tension by applanation (applying a small flat disk to the cornea). Accessories for the device may include a tonometer calibrator or a tonograph recording system. The device is intended for use in the diagnosis of glaucoma.
(b) Classification. Class II.

§ 886.1940 Tonometer sterilizer.
(a) Identification. A tonometer sterilizer is an AC-powered device intended to heat sterilize a tonometer (a device used to measure intraocular pressure).
(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 §886.9.


§ 886.1945 Transilluminator.
(a) Identification. A transilluminator is an AC-powered or battery-powered device that is a light source intended to transmit light through tissues to aid examination of patients.
(b) Classification. Class I for the battery-powered device. The battery-powered device is also exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in §886.9. Class II for the AC-powered device.


Subpart C [Reserved]

Subpart D—Prosthetic Devices

§ 886.3100 Ophthalmic tantalum clip.
(a) Identification. An ophthalmic tantalum clip is a malleable metallic device intended to be implanted permanently or temporarily to bring together the edges of a wound to aid healing or prevent bleeding from small blood vessels in the eye.
(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 §886.9.


§ 886.3130 Ophthalmic conformer.
(a) Identification. An ophthalmic conformer is a device usually made of molded plastic intended to be inserted temporarily between the eyeball and eyelid to maintain space in the orbital cavity and prevent closure or adhesions during the healing process following surgery.
(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 §886.9.

§ 886.3200 Artificial eye.

(a) Identification. An artificial eye is a device resembling the anterior portion of the eye, usually made of glass or plastic, intended to be inserted in a patient’s eye socket anterior to an orbital implant, or the eviscerated eyeball, for cosmetic purposes. The device is not intended to be implanted.

(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 §886.9, if the device is made from the same materials, has the same chemical composition, and uses the same manufacturing processes as currently legally marketed devices.


§ 886.3300 Absorbable implant (scleral buckling method).

(a) Identification. An absorbable implant (scleral buckling method) is a device intended to be implanted on the sclera to aid retinal reattachment.

(b) Classification. Class II.

§ 886.3320 Eye sphere implant.

(a) Identification. An eye sphere implant is a device intended to be implanted in the eyeball to occupy space following the removal of the contents of the eyeball with the sclera left intact.

(b) Classification. Class II.

§ 886.3340 Extraocular orbital implant.

(a) Identification. An extraocular orbital implant is a nonabsorbable device intended to be implanted during scleral surgery for buckling or building up the floor of the eye, usually in conjunction with retinal reattachment. Injectable substances are excluded.

(b) Classification. Class II.

§ 886.3400 Keratoprosthesis.

(a) Identification. A keratoprosthesis is a device intended to provide a transparent optical pathway through an opacified cornea, either intraoperatively or permanently, in an eye that is not a reasonable candidate for a corneal transplant.

(b) Classification. Class II. The special controls for this device are FDA’s:


(2) “510(k) Sterility Review Guidance of 2/12/90 (K90–1),’’ and

(3) “Guidance on 510(k) Submissions for Keratoprosthesis.”

[65 FR 17147, Mar. 31, 2000]

§ 886.3600 Intraocular lens.

(a) Identification. An intraocular lens is a device made of materials such as glass or plastic intended to be implanted to replace the natural lens of an eye.

(b) Classification. Class II.

§ 886.3800 Scleral shell.

(a) Identification. A scleral shell is a device made of glass or plastic that is intended to be inserted for short time periods over the cornea and proximal cornea sclera for cosmetic or reconstructive purposes. An artificial eye is usually painted on the device. The device is not intended to be implanted.

(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 §886.9.


§ 886.3920 Aqueous shunt.

(a) Identification. An aqueous shunt is an implantable device intended to reduce intraocular pressure in the anterior chamber of the eye in patients with neovascular glaucoma or with glaucoma when medical and conventional surgical treatments have failed.

(b) Classification. Class II. The special controls for this device are FDA’s:


(2) “510(k) Sterility Review Guidance of 2/12/90 (K90–1),’’ and
Subpart E—Surgical Devices

§ 886.4070 Powered corneal burr.

(a) Identification. A powered corneal burr is an AC-powered or battery-powered device that is a motor and drilling tool intended to remove rust rings from the cornea of the eye.

(b) Classification. Class I (general controls). When intended only for rust ring removal, the device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 886.9.

§ 886.4100 Radiofrequency electrosurgical cautery apparatus.

(a) Identification. A radiofrequency electrosurgical cautery apparatus is an AC-powered or battery-powered device intended for use during ocular surgery to coagulate tissue or arrest bleeding by a high frequency electric current.

(b) Classification. Class II.

§ 886.4115 Thermal cautery unit.

(a) Identification. A thermal cautery unit is an AC-powered or battery-powered device intended for use during ocular surgery to coagulate tissue or arrest bleeding by heat conducted through a wire tip.

(b) Classification. Class II.

§ 886.4150 Vitreous aspiration and cutting instrument.

(a) Identification. A vitreous aspiration and cutting instrument is an electrically powered device, which may use ultrasound, intended to remove vitreous matter from the vitreous cavity or remove a crystalline lens.

(b) Classification. Class II.

§ 886.4155 Scleral plug.

(a) Identification. A scleral plug is a prescription device intended to provide temporary closure of a scleral incision during an ophthalmic surgical procedure. These plugs prevent intraocular fluid and pressure loss when instruments are withdrawn from the eye. Scleral plugs include a head portion remaining above the sclera, which can be gripped for insertion and removal, and a shaft that fits inside the scleral incision. Scleral plugs are removed before completing the surgery.

(b) Classification. Class II (special controls). The special controls for the scleral plug are as follows:

(1) The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 886.9 if the material is a surgical grade stainless steel with or without a gold, silver, or titanium coating. The special controls for the surgical grade stainless steel scleral plug (with or without a gold, silver, or titanium coating) are:

(i) The device must be demonstrated to be sterile during the labeled shelf life;

(ii) The device must be demonstrated to be biocompatible; and

(iii) Labeling must include all information required for the safe and effective use of the device, including specific instructions regarding the proper sizing, placement, and removal of the device.

(2) The device is not exempt from premarket notification procedures if it is composed of a material other than surgical grade stainless steel (with or without a gold, silver, or titanium coating). The special controls for scleral plugs made of other materials are:

(i) The device must be demonstrated to be sterile during the labeled shelf life;

(ii) The device must be demonstrated to be biocompatible;

(iii) Characterization of the device materials must be performed;

(iv) Performance data must demonstrate acceptable mechanical properties under simulated clinical use conditions including insertion and removal of the device;

(v) Performance data must demonstrate adequately low levels of the extractables or residues from manufacturing (or processing) of the device; and
§ 886.4170  [21 CFR Ch. I (4–1–16 Edition)]

(vi) Labeling must include all information required for the safe and effective use of the device, including specific instructions regarding the proper sizing, placement, and removal of the device.

[78 FR 68715, Nov. 15, 2013]

§ 886.4170 Cryophthalmic unit.

(a) Identification. A cryophthalmic unit is a device that is a probe with a small tip that becomes extremely cold through the controlled use of a refrigerant or gas. The device may be AC-powered. The device is intended to remove cataracts by the formation of an adherent ice ball in the lens, to freeze the eye and adjacent parts for surgical removal of scars, and to freeze tumors.

(b) Classification. Class II.

§ 886.4230 Ophthalmic knife test drum.

(a) Identification. An ophthalmic knife test drum is a device intended to test the keenness of ophthalmic surgical knives to determine whether re-sharpening is needed.

(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 §886.9.

§ 886.4250 Ophthalmic electrolysis unit.

(a) Identification. An ophthalmic electrolysis unit is an AC-powered or battery-powered device intended to destroy ocular hair follicles by applying a galvanic electrical current.

(b) Classification. Class I for the battery-powered device. Class II for the AC-powered device. The battery-powered device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in §886.9.


§ 886.4270 Intraocular gas.

(a) Identification. An intraocular gas is a device consisting of a gaseous fluid intended to be introduced into the eye to place pressure on a detached retina.

(b) Classification. Class III.

(c) Date PMA or notice of completion of a PDP is required. As of May 28, 1976, an approval under section 515 of the act is required before this device may be commercially distributed. See §886.3.

§ 886.4275 Intraocular fluid.

(a) Identification. An intraocular fluid is a device consisting of a nongaseous fluid intended to be introduced into the eye to aid performance of surgery, such as to maintain anterior chamber depth, preserve tissue integrity, protect tissue from surgical trauma, or function as a tamponade during retinal reattachment.

(b) Classification. Class III.

(c) Date PMA or notice of completion of a PDP is required. As of May 28, 1976, an approval under section 515 of the act is required before this device may be commercially distributed. See §886.3.

§ 886.4280 Intraocular pressure measuring device.

(a) Identification. An intraocular pressure measuring device is a manual or AC-powered device intended to measure intraocular pressure. Also included are any devices found by FDA to be substantially equivalent to such devices. Accessories for the device may include calibrators or recorders. The device is intended for use in the diagnosis of glaucoma.

(b) Classification. Class III.

(c) Date PMA or notice of completion of a PDP is required. As of May 28, 1976, an approval under section 515 of the act is required before this device may be commercially distributed. See §886.3.

§ 886.4300 Intraocular lens guide.

(a) Identification. An intraocular lens guide is a device intended to be inserted into the eye during surgery to direct the insertion of an intraocular
lens and be removed after insertion is completed.

(b) Classification. Class I (general controls). Except when used as folders or injectors for soft or foldable intraocular lenses, the device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to §886.9.

§ 886.4335 Operating headlamp.

(a) Identification. An operating headlamp is an AC-powered or battery-powered device intended to be worn on the user’s head to provide a light source to aid visualization during surgical, diagnostic, or therapeutic procedures.

(b) Classification. Class I for the battery-powered device. Class II for the AC-powered device. The battery-powered device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in §886.9.

§ 886.4350 Manual ophthalmic surgical instrument.

(a) Identification. A manual ophthalmic surgical instrument is a non-powered, handheld device intended to aid or perform ophthalmic surgical procedures. This generic type of device includes the manual corneal Burr, ophthalmic caliper, ophthalmic cannula, eyelid clamp, ophthalmic muscle clamp, iris retractor clip, orbital compressor, ophthalmic curette, cystotome, orbital depressor, lachrymal dilator, erisophake, expressor, ophthalmic forcep, ophthalmic hook, sphere introducer, ophthalmic knife, ophthalmic suturing needle, lachrymal probe, trabeculotony probe, corneosclera punch, ophthalmic retractor, ophthalmic ring (Flieringa), lachrymal sac rongeur, ophthalmic scissors, enucleating snare, ophthalmic spatula, ophthalmic specula, ophthalmic spoon, ophthalmic spud, trabeculotome or ophthalmic manual trephine.

(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 §886.9.

§ 886.4360 Ocular surgery irrigation device.

(a) Identification. An ocular surgery irrigation device is a device intended to be suspended over the ocular area during ophthalmic surgery to deliver continuous, controlled irrigation to the surgical field.

(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 §886.9.

§ 886.4370 Keratome.

(a) Identification. A keratome is an AC-powered or battery-powered device intended to shave tissue from sections of the cornea for a lamellar (partial thickness) transplant.

(b) Classification. Class I.

§ 886.4390 Ophthalmic laser.

(a) Identification. An ophthalmic laser is an AC-powered device intended to coagulate or cut tissue of the eye, orbit, or surrounding skin by a laser beam.

(b) Classification. Class II.

§ 886.4392 Nd:YAG laser for posterior capsulotomy and peripheral iridotomy.

(a) Identification. The Nd:YAG laser for posterior capsulotomy and peripheral iridotomy consists of a mode-locked or Q-switched solid state Nd:YAG laser intended for disruption of the posterior capsule or the iris via optical breakdown. The Nd:YAG laser generates short pulse, low energy, high power, coherent optical radiation. When the laser output is combined with focusing optics, the high irradiance at the target causes tissue disruption via optical breakdown. A visible aiming system is utilized to target the
§ 886.4400 Invisible Nd:YAG laser radiation on or in close proximity to the target tissue.

(b) Classification. Class II (special controls). Design Parameters: Device must emit a laser beam with the following parameters: wavelength = 1064 nanometers; spot size = 50 to 100 micros; pulse width = 3 to 30 nanoseconds; output energy per pulse = 0.5 to 15 millijoules (mJ); repetition rate = 1 to 10 pulses; and total energy = 20 to 120 mJ.

[65 FR 6894, Feb. 11, 2000]

§ 886.4400 Electronic metal locator.

(a) Identification. An electronic metal locator is an AC-powered device with probes intended to locate metallic foreign bodies in the eye or eye socket.

(b) Classification. Class II.

§ 886.4440 AC-powered magnet.

(a) Identification. An AC-powered magnet is an AC-powered device that generates a magnetic field intended to find and remove metallic foreign bodies from eye tissue.

(b) Classification. Class II.

§ 886.4445 Permanent magnet.

(a) Identification. A permanent magnet is a nonelectric device that generates a magnetic field intended to find and remove metallic foreign bodies from eye tissue.

(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 §886.9.


§ 886.4460 Ocular pressure applicator.

(a) Identification. An ocular pressure applicator is a manual device that consists of a sphygmomanometer type squeeze bulb, a dial indicator, a band, and bellows, intended to apply pressure on the eye in preparation for ophthalmic surgery.

(b) Classification. Class II.

§ 886.4670 Phacofragmentation system.

(a) Identification. A phacofragmentation system is an AC-powered device with a fragmenting needle intended for use in cataract surgery to disrupt a cataract with ultrasound and extract the cataract.

(b) Classification. Class II.

§ 886.4690 Ophthalmic photocoagulator.

(a) Identification. An ophthalmic photocoagulator is an AC-powered device intended to use the energy from an extended noncoherent light source to occlude blood vessels of the retina, choroid, or iris.

(b) Classification. Class II.

§ 886.4750 Ophthalmic eye shield.

(a) Identification. An ophthalmic eye shield is a device that consists of a plastic or aluminum eye covering intended to protect the eye or retain dressing materials in place.

(b) Classification. Class I (general controls). When made only of plastic or aluminum, the device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to §886.9. When made only of plastic or aluminum, the devices are exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of §820.180 of this chapter, with respect to general requirements concerning the location of ocular or scleral surgical manipulation.

§ 886.4610 Ocular pressure applicator.

(a) Identification. An ocular pressure applicator is a manual device that consists of a sphygmomanometer type squeeze bulb, a dial indicator, a band, and bellows, intended to apply pressure on the eye in preparation for ophthalmic surgery.

(b) Classification. Class II.

§ 886.4670 Phacofragmentation system.

(a) Identification. A phacofragmentation system is an AC-powered device with a fragmenting needle intended for use in cataract surgery to disrupt a cataract with ultrasound and extract the cataract.

(b) Classification. Class II.

§ 886.4690 Ophthalmic photocoagulator.

(a) Identification. An ophthalmic photocoagulator is an AC-powered device intended to use the energy from an extended noncoherent light source to occlude blood vessels of the retina, choroid, or iris.

(b) Classification. Class II.

§ 886.4750 Ophthalmic eye shield.

(a) Identification. An ophthalmic eye shield is a device that consists of a plastic or aluminum eye covering intended to protect the eye or retain dressing materials in place.

(b) Classification. Class I (general controls). When made only of plastic or aluminum, the device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to §886.9. When made only of plastic or aluminum, the devices are exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of §820.180 of this chapter, with respect to general requirements concerning
Food and Drug Administration, HHS § 886.4770 Ophthalmic operating spectacles (loupes).

(a) Identification. Ophthalmic operating spectacles (loupes) are devices that consist of convex lenses or lens systems intended to be worn by a surgeon to magnify the surgical site during ophthalmic surgery.

(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 §886.9. The device is also exempt from the current good manufacturing practice requirements of the quality system regulation 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.


§ 886.4790 Ophthalmic sponge.

(a) Identification. An ophthalmic sponge is a device that is an absorbant sponge, pad, or spear made of folded gauze, cotton, cellulose, or other material intended to absorb fluids from the operative field in ophthalmic surgery.

(b) Classification. Class II.

§ 886.4855 Ophthalmic instrument table.

(a) Identification. An ophthalmic instrument table is an AC-powered or manual device on which ophthalmic instruments are intended to be placed.

(b) Classification. Class I (general controls). The AC-powered device and the manual device are exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in §886.9. The manual device is also exempt from the current good manufacturing practice requirements of the quality system regulation 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.


Subpart F—Therapeutic Devices

§ 886.5100 Ophthalmic beta radiation source.

(a) Identification. An ophthalmic beta radiation source is a device intended to apply superficial radiation to benign and malignant ocular growths.

(b) Classification. Class II.

§ 886.5120 Low-power binocular loupe.

(a) Identification. A low-power binocular loupe is a device that consists of two eyepieces, each with a lens or lens system, intended for medical purposes to magnify the appearance of objects.

(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 §886.9. The device is also exempt from the current good manufacturing practice requirements of the quality system regulation 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.


§ 886.5200 Eyelid thermal pulsation system.

(a) Identification. An eyelid thermal pulsation system is an electrically-powered device intended for use in the application of localized heat and pressure therapy to the eyelids. The device is used in adult patients with chronic cystic conditions of the eyelids, including meibomian gland dysfunction (MGD), also known as evaporative dry eye or lipid deficiency dry eye. The system consists of a component that is inserted around the eyelids and a component to control the application of heat and pressure to the eyelids.

(b) Classification. Class II (special controls). The special controls for this device are:
§ 886.5420  Contact lens inserter/remover.

(a) Identification. A contact lens inserter/remover is a handheld device intended to insert or remove contact lenses by surface adhesion or suction.

(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 § 886.9.

§ 886.5540  Low-vision magnifier.

(a) Identification. A low-vision magnifier is a device that consists of a magnifying lens intended for use by a patient who has impaired vision. The device may be held in the hand or attached to spectacles.

(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 § 886.9.

§ 886.5700  Eyelid weight.

(a) Identification. An eyelid weight is a prescription device made of gold, tantalum, platinum, iridium, or surgical grade stainless steel that is rectangular in shape and contoured to the shape of the eye. The device is intended for the gravity assisted treatment of lagophthalmos (incomplete eyelid closure).

(1) The external eyelid weight is adhered to the outer skin of the upper eyelid.

(2) The implantable eyelid weight is implanted into the upper eyelid.

(b) Classification. (1) Class II (special controls) for the external eyelid weight. The external eyelid weight is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 886.9. The special controls for the external eyelid weight are:

(i) Testing demonstrating the biocompatibility of the device; and

(ii) Labeling must include the following information:
§ 886.5840 Spectacle frame.

(a) Identification. A spectacle frame is a device made of metal or plastic intended to hold prescription spectacle lenses worn by a patient to correct refractive errors.

(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 §886.9. The device is also exempt from the current good manufacturing practice requirements of the quality system regulation 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.


§ 886.5842 Spectacle frame.

(a) Identification. A spectacle frame is a device made of metal or plastic intended to hold prescription spectacle lenses worn by a patient to correct refractive errors.

(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 §886.9. The device is also exempt from the current good manufacturing practice requirements of the quality system regulation 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.

§ 886.5844 Prescription spectacle lens.

(a) Identification. A prescription spectacle lens is a glass or plastic device that is a lens intended to be worn by a patient in a spectacle frame to provide refractive corrections in accordance with a prescription for the patient. The device may be modified to protect the eyes from bright sunlight (i.e., prescription sunglasses). Prescription sunglasses lenses may be reflective, tinted, polarizing, or photosensitized.

(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 §886.9.


§ 886.5850 Sunglasses (nonprescription).

(a) Identification. Sunglasses (nonprescription) are devices that consist of spectacle frames or clips with absorbing, reflective, tinted, polarizing, or photosensitized lenses intended to be worn by a person to protect the eyes from bright sunlight but not to provide refractive corrections. This device is usually available over-the-counter.

(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 §886.9.


§ 886.5900 Electronic vision aid.

(a) Identification. An electronic vision aid is an AC-powered or battery-powered device that consists of an electronic sensor/transducer intended for use by a patient who has impaired vision or blindness to translate visual images of objects into tactile or auditory signals.

(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 §886.9.


§ 886.5905 Oral electronic vision aid.

(a) Identification. An oral electronic vision aid is a battery-powered prescription device that contains an electrode stimulation array to generate electrotactile stimulation patterns that are derived from digital object images captured by a camera. It is intended to aid profoundly blind patients in orientation, mobility, and object recognition as an adjunctive device to other assistive methods such as a white cane or a guide dog.

(b) Classification. Class II (special controls). The special controls for this device are:

(1) Clinical performance testing must demonstrate an acceptable adverse event profile, including adverse events involving the mouth, tongue, and gums and demonstrate the effect of the stimulation to provide clinically meaningful outcomes. The clinical performance
testing must also investigate the anticipated conditions of use, including potential use error, intended environment of use, and duration of use.

(2) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use, including simulated moisture ingress, device durability, and battery reliability.

(3) Software verification, validation, and hazard analysis must be performed.

(4) Analysis/testing must validate electromagnetic compatibility.

(5) Analysis/testing must validate electrical safety.

(6) Analysis/testing must assess and validate wireless coexistence concerns.

(7) Any elements of the device that contact the patient must be demonstrated to be biocompatible.

(8) Training must include elements to ensure that the healthcare provider and user can identify the safe environments for device use, use all safety features of the device, and operate the device in the intended environment of use.

(9) Labeling for the trainer and user must include a summary of the clinical testing including adverse events encountered under use conditions, summary of study outcomes and endpoints, and information pertinent to use of the device including the conditions under which the device was studied (e.g., level of supervision or assistance, and environment of use).

§ 886.5910 Image intensification vision aid.

(a) Identification. An image intensification vision aid is a battery-powered device intended for use by a patient who has limited dark adaptation or impaired vision to amplify ambient 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 §886.9. The device is also exempt from the current good manufacturing practice requirements of the quality system regulation 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.

§ 886.5915 Optical vision aid.

(a) Identification. An optical vision aid is a device that consists of a magnifying lens with an accompanying AC-powered or battery-powered light source intended for use by a patient who has impaired vision to increase the apparent size of object detail.

(b) Classification. Class I (general controls). The AC-powered device and the battery-powered device are exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in §886.9. The battery-powered device is also exempt from the current good manufacturing practice requirements of the quality system regulation 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.

§ 886.5916 Rigid gas permeable contact lens.

(a) Identification. A rigid gas permeable contact lens is a device intended to be worn directly against the cornea of the eye to correct vision conditions. The device is made of various materials, such as cellulose acetate butyrate, polyacrylate-silicone, or silicone elastomers, whose main polymer molecules generally do not absorb or attract water.

(b) Classification. Class II if the device is intended for daily wear only.

(c) Date PMA or notice of completion of a PDP is required. As of May 28, 1976, an approval under section 515 of the act is required before a device described in paragraph (b)(2) of this section may be commercially distributed. See §886.3.

Perry A. Wiggins, Administrator.


§ 886.5918 Rigid gas permeable contact lens care products.

(a) Identification. A rigid gas permeable contact lens care product is a device intended for use in the cleaning, conditioning, rinsing, lubricating/rewetting, or storing of a rigid gas permeable contact lens. This includes all solutions and tablets used together with rigid gas permeable contact lenses.

(b) Classification. Class II (Special Controls) Guidance Document: “Guidance for Industry Premarket Notification (510(k)) Guidance Document for Contact Lens Care Products.”


§ 886.5925 Soft (hydrophilic) contact lens.

(a) Identification. A soft (hydrophilic) contact lens is a device intended to be worn directly against the cornea and adjacent limbal and scleral areas of the eye to correct vision conditions or act as a therapeutic bandage. The device is made of various polymer materials the main polymer molecules of which absorb or attract a certain volume (percentage) of water.

(b) Classification. (1) Class II if the device is intended for daily wear only.

(2) Class III if the device is intended for extended wear.

(c) Date PMA or notice of completion of a PDP is required. As of May 28, 1976, an approval under section 515 of the act is required before a device described in paragraph (b)(2) of this section may be commercially distributed. See § 886.3.


§ 886.5928 Soft (hydrophilic) contact lens care products.

(a) Identification. A soft (hydrophilic) contact lens care product is a device intended for use in the cleaning, rinsing, disinfecting, lubricating/rewetting, or storing of a soft (hydrophilic) contact lens. This includes all solutions and tablets used together with soft (hydrophilic) contact lenses by means of heat.

(b) Classification. Class II (Special Controls) Guidance Document: “Guidance for Industry Premarket Notification (510(k)) Guidance Document for Contact Lens Care Products.”


§ 886.5933 [Reserved]

PART 888—ORTHOPEDIC DEVICES

Subpart A—General Provisions

Sec.
888.1 Scope.
888.3 Effective dates of requirement for premarket approval.
888.5 Resurfacing technique.
888.6 Degree of constraint.
888.9 Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).

Subpart B—Diagnostic Devices

888.1100 Arthroscope.
888.1240 AC-powered dynamometer.
888.1250 Nonpowered dynamometer.
888.1500 Goniometer.
888.1520 Nonpowered goniometer.

Subpart C [Reserved]

Subpart D—Prosthetic Devices

888.3000 Bone cap.
888.3010 Bone fixation cerclage.
888.3015 Bone heterograft.
888.3020 Intramedullary fixation rod.
888.3025 Passive tendon prosthesis.
888.3027 Polymethylmethacrylate (PMMA) bone cement.
888.3030 Single/multiple component metallic bone fixation appliances and accessories.
888.3040 Smooth or threaded metallic bone fixation fastener.
888.3045 Resorbable calcium salt bone void filler device.
888.3050 Spinal interlaminar fixation orthosis.
888.3060 Spinal intervertebral body fixation orthosis.
888.3070 Pedicle screw spinal system.
888.3080 Intervertebral body fusion device.
888.3100 Ankle joint metal/composite semi-constrained cemented prosthesis.
888.3110 Ankle joint metal/polymer semi-constrained cemented prosthesis.
888.3120 Ankle joint metal/polymer non-constrained cemented prosthesis.
888.3150 Elbow joint metal/polymer constrained cemented prosthesis.
888.3160 Elbow joint metal/polymer semi-constrained cemented prosthesis.
888.3170 Elbow joint radial (hemi-elbow) polymer prosthesis.
888.3180 Elbow joint humeral (hemi-elbow) metal/metal uncemented prosthesis.