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21 CFR Parts 872 et al.

Medical Devices; Proposed Classifications of 70 Electromedical Devices; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 872, 874, 878, 884, 886, 888, and 892

[Docket No. 78N-2847 et al.]

Medical Devices; Reproposed Classifications of 70 Electromedical Devices

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is reproposing the regulations to classify 70 electromedical devices of a type on the market before the Medical Device Amendments of 1976. In six previous proposed rules, FDA proposed to classify these devices into class II, the category of medical devices for which performance standards, as well as general controls, are contemplated. If FDA adopts a final rule based on this reproposal, the agency would classify the 70 devices into class I, the category of medical devices required to meet only the general controls of the Federal Food, Drug, and Cosmetic Act.

DATES: Comments by January 17, 1989. FDA is proposing that any final rule based on this proposed rule would become effective 30 days after its date of publication in the Federal Register.

ADDRESS: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Joseph M. Sheehan, Center for Devices and Radiological Health (HFZ-84), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4874.

SUPPLEMENTARY INFORMATION:

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A. Background

Classification of medical devices in commercial distribution is required by section 513 of the Medical Device Amendments of 1976 (Pub. L. 94-295) (the amendments) to the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c). The effect of classifying a device into class I is to require that the device continue to meet only the general controls applicable to all devices. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. The effect of classifying a device into class III is to require each manufacturer of the device to submit to FDA a premarket approval application that includes information concerning safety and effectiveness tests for the device.

Pursuant to section 513, FDA has published a series of proposed and final rules classifying devices which were in commercial distribution when the amendments were enacted (i.e., classifying preamendments devices and devices determined by FDA to be substantially equivalent to such devices). For purposes of classification, FDA categorized such devices into 16 medical specialty groups. By 1983, FDA had promulgated final rules classifying preamendments devices for 9 of the 16 medical specialty groups. In those nine rules, FDA classified most AC-powered devices into class II, and few comments had been received on the proposals that had preceded these classifications.

In 1980 and 1982, when FDA published the remaining seven proposed rules to classify devices, many comments were received which recommended that AC-powered devices be classified into class I instead of class II. The comments stated that the risks to health presented by electrical shock or leakage current from an AC-powered device could be controlled by the general controls of class I and that establishment of performance standards under section 514 of the act (21 U.S.C. 360d) for such AC-powered devices is unnecessary.

During the same period, as part of FDA's implementation of the amendments, FDA began to develop and evaluate its procedures and priorities for the establishment of performance standards for the hundreds of devices already classified into class II in the nine published final rules and for the devices that had been proposed for classification into class II in the seven remaining rulemaking proceedings. Based in part on the agency's evaluation of its procedures and priorities and its review of comments on the seven remaining proposed classification rules, FDA determined to reconsider its standards policy. As a result of this policy reconsideration, FDA published in the Federal Register of October 23, 1985 (50 FR 43060), its policy for setting priorities for initiating proceedings to establish performance standards for medical devices classified into class II.

In the Federal Register of September 5, 1980 (45 FR 58970), FDA had published a notice of intent announcing that it would consider various alternative approaches in providing reasonable assurance of the safety and effectiveness of electromedical devices. To minimize electrical hazards, especially the hazard of electrical leakage current, FDA announced that it would consider three alternatives: establishing performance standards under section 514 of the act (21 U.S.C. 360d), endorsement of voluntary standards, or adoption of a guideline for electromedical devices. In the Federal Register of October 15, 1987 (52 FR 38276), FDA published a withdrawal of its notice of intent of September 5, 1980 (45 FR 58970). FDA's reasons for publishing the withdrawal are given in the 1987 document. FDA's withdrawal of that notice of intent is consistent with its tentative policy regarding classification of electromedical devices expressed in this reproposal.

In further implementation of its tentative policy of classifying AC-powered devices into class I, FDA, in six of the remaining final rules classifying preamendments devices, classified into class II only those AC-powered devices which present risks to health in addition to the risk of electrical leakage current. In those rules, FDA stated that it was postponing the classification of certain AC-powered devices which present only the risk of electrical leakage current and announced its tentative plans to repropose classification of these devices into class I.

Accordingly, in this reproposed rule, FDA is proposing to classify into class I the AC-powered devices whose classifications were omitted from the six final rules listed below:

Dental Devices

Proposed rule (Federal Register of December 30,1980; 45 FR 85962)
Final rule (Federal Register of August 12, 1987; 52 FR 30082)

Ear, Nose, and Throat Devices

Proposed rule (Federal Register of January 22, 1982; 47 FR 3280)
Final rule (Federal Register of November 6, 1986; 51 FR 40378)

General and Plastic Surgery Devices

Proposed rule (Federal Register of January 19, 1982; 47 FR 2810)
Final rule (Federal Register of June 24, 1988; 53 FR 23856)

Ophthalmic Devices

Proposed rule (Federal Register of January 26, 1982; 47 FR 3694)
Final rule (Federal Register of September 2, 1987; 52 FR 33346)

Orthopedic Devices

Proposed rule (Federal Register of July 2, 1982; 47 FR 29052)

Final rule (Federal Register of September 4, 1987; 52 FR 33686)

Radiology Devices

Proposed rule (Federal Register of January 29, 1982; 47 FR 4406)

Final rule (Federal Register of January 20, 1988; 53 FR 1554)

In 1980 and 1982, when FDA published the six proposed rules listed above, the agency had also published the recommendations of the six advisory committees (Panels) for these devices, as required by section 513 (c)(2) and (d)(1) of the act (21 U.S.C. 360 (c)(2) and (d)(1)). Because FDA has already published these Panel recommendations in the Federal Register, the agency believes it unnecessary to repeat the detailed recommendations for each device here. Essentially, FDA had originally proposed that all of the devices which are the subject of this proposed rule be classified into class II. FDA now is reproposing that these devices be classified into class I and is requesting comments on its reproposal. Some of the regulations would include both the AC-powered device proposed for classification and its already-classified non-AC-powered counterpart.

B. List of Reproposed Classifications

FDA is proposing that the following AC-powered devices be classified into class I:

Section and Device	Docket No.
Part 872—Dental Devices	
872.3100—Dental Amalgamator	78N-2847
872.3530—Mechanical denture cleaner	78N-2879
872.4200—Dental handpiece and accessories	78N-2918
872.4620—Fiber optic dental light	78N-2934
872.6250—Dental chair and accessories	78N-2980
872.6475—Heat source for bleaching teeth	78N-2994
872.6510—Oral irrigation unit	78N-2996
872.6640—Dental operative unit and accessories	78N-3002
872.6710—Boiling water sterilizer	78N-3009
872.6865—Powered toothbrush	78N-3020
Part 874—Ear, Nose, and Throat Devices	
874.1070—Short increment sensitivity index (SISI) adapter	78N-1552
874.1800—Air or water caloric stimulator	78N-1565
874.4750—Laryngostroboscope	78N-1622
874.4770—Otoscope	78N-1624
874.5300—Ear, nose, and throat examination and treatment unit	78N-1630
874.5550—Powered nasal irrigator	78N-1631
Part 878—General and Plastic Surgery Devices	
878.4635—Ultraviolet lamp for tanning	78N-2687
878.4700—Surgical microscope and accessories	78N-2691
878.4820—Surgical instrument motors and accessories/attachments	78N-2698
878.4960—Operating tables and accessories and operating chairs and accessories	78N-2705
Part 884—Obstetrical and Gynecological Devices	
884.2980—Telethermographic system	78N-2762
884.2982—Liquid crystal thermographic system	78N-2763
Part 886—Opthalmic Devices	
886.1050—Adaptometer (biophotometer)	78N-3130
886.1070—Anomaloscope	78N-3132
886.1090—Haidlinger brush	78N-3133
886.1120—Opthalmic camera	78N-3135
886.1140—Ophthalmic chair	78N-3137
886.1160—Color vision plate illuminator	78N-3140
886.1250—Euthyscope	78N-3145
886.1290—Fixation device	78N-3148
886.1300—Afterimage flasher	78N-3149
886.1340—Hapscope	78N-3295
886.1350—Keratoscope	78N-3153
886.1425—Lens measuring instrument	78N-3166
886.1430—Ophthalmic contact lens radius measuring device	78N-3167
886.1435—Maxwell spot	78N-3168
886.1450—Corneal radius measuring device	78N-3169
886.1605—Perimeter	78N-3178
886.1680—Ophthalmic projector	78N-3189
886.1690—Pupillograph	78N-3190
886.1700—Pupillometer	78N-3191
886.1780—Retinoscope	78N-3196
886.1810—Tangent screen (campimeter)	78N-3200
886.1860—Opthalmic instrument stand	78N-3208
886.1870—Stereoscope	78N-3210
886.1910—Spectacle dissociation test system	78N-3214
886.1940—Tonometer sterilizer	78N-3220
886.1945—Transilluminator	78N-3221
886.4070—Powered corneal burr	78N-3233
886.4250—Ophthalmic electrolysis unit	78N-3244
886.4335—Operating headlamp	78N-3252
886.4370—Keratome	78N-3255
886.4855—Ophthalmic instrument table	78N-3272
886.5820—Closed-circuit television reading system	78N-3285
886.5900—Electronic vision aid	78N-3290
886.5915—Optical vision aid	78N-3293
Part 888—Orthopedic Devices	
888.1500—Goniometer	78N-3043
888.5960—Cast removal instrument	78N-3124
Part 892—Radiology Devices	
892.1100—Scintillation (gamma) camera	78N-2743
892.1110—Positron camera	78N-2744
892.1130—Nuclear whole body counter	78N-2745
892.1300—Nuclear rectilinear scanner	78N-2750
892.1320—Nuclear uptake probe	78N-2752
892.1330—Nuclear whole body scanner	78N-2753
892.1350—Nuclear scanning bed	78N-2754
892.1410—Nuclear electrocardiograph synchronizer	78N-2760
892.1640—Radiographic film marking system	78N-2773
892.1890—Radiographic film illuminator	78N-2795
892.1900—Automatic radiographic film processor	78N-2796
892.1970—Radiographic ECG/respirator synchronizer	78N-2803

C. Exemptions

The Panels had recommended that all of the devices which would be classified into class I by this proposed rule should be subject to all of the controls of the current good manufacturing practice regulations at 21 CFR Part 820. FDA believes that all of the controls provided by Part 820 are necessary to provide reasonable assurance of the safety and effectiveness of these AC-powered devices. Accordingly, FDA is not proposing that any exemptions from Part 820 be granted for manufacturers of any of these devices.

D. Environmental Impact

The agency has determined under 21 CFR 25.24(e)(2) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

E. Economic Impact

FDA has carefully analyzed the economic effects of this proposed rule and has determined that the proposed rule will not have a significant economic impact on a substantial number of small entities as defined by the Regulatory Flexibility Act. In accordance with section 3(g)(1) of Executive Order 12291, the impact of this proposed rule has been carefully analyzed, and it has been determined that the proposed rule does not constitute a major rule as defined in section 1(b) of the Executive Order. Rules classifying devices into class I generally maintain the status quo: These devices are now subject only to the general controls provisions of the act (21 U.S.C. 351, 352, 360, 360f, 360h, 360i, and 360j) and under the final rule would remain subject only to such controls. Devices classified into class II also remain subject only to the general controls provisions of the act unless and until an applicable performance standard is established. In sum, device classification rules do not have a significant impact on a substantial number of small entities and are not major rules.

Interested persons may, on or before January 17, 1989, submit to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received

comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects

21 CFR Part 872

Medical devices.

21 CFR Part 874

Medical devices.

21 CFR Part 878

Medical devices.

21 CFR Part 884

Medical devices.

21 CFR Part 886

Medical devices, Ophthalmic goods and services.

21 CFR Part 888

Medical devices.

21 CFR Part 892

Medical devices, Radiation protection, X-rays.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that Chapter I of Title 21 of the Code of Federal Regulations, Parts 872, 874, 878, 884, 886, 888, and 892, be amended to read as follows:

PART 872—DENTAL DEVICES

1. The authority citation for 21 CFR Part 872 continues to read as follows:

Authority: Secs. 501(f), 510, 513, 515, 520, 701(a), 52 Stat. 1055, 76 Stat. 794–795 as amended, 90 Stat. 540–546, 552–559, 565–574, 576–577 (21 U.S.C. 351(f), 360, 360c, 360e, 360j, 371(a)); 21 CFR 5.10.

2. Section 872.3100 is added to Subpart D to read as follows:

§ 872.3100 Dental amalgamator.

(a) *Identification.* A dental amalgamator is a device, usually AC-powered, intended to mix, by shaking, amalgam capsules containing mercury and dental alloy particles, such as silver, tin, zinc, and copper. The mixed dental amalgam material is intended for filling dental caries.

(b) *Classification.* Class I.

3. Section 872.3530 is added to Subpart D to read as follows:

§ 872.3530 Mechanical denture cleaner.

(a) *Identification.* A mechanical denture cleaner is a device, usually AC-powered, that consists of a container for mechanically agitating a denture cleansing solution. The device is intended to clean a denture by submersion in the agitating cleansing solution in the container.

(b) *Classification.* Class I.

4. Section 872.4200 is added to Subpart E to read as follows:

§ 872.4200 Dental handpiece and accessories.

(a) *Identification.* A dental handpiece and accessories is an AC-powered, water-powered, air-powered, or belt-driven hand-held device that may include a foot controller for regulation of speed and direction of rotation or a contraangle attachment for difficult to reach areas intended to prepare dental cavities for restorations, such as fillings, and for cleaning teeth.

(b) *Classification.* Class I.

5. Section 872.4620 is added to Subpart E to read as follows:

§ 872.4620 Fiber optic dental light.

(a) *Identification.* A fiber optic dental light is a device that is a light, usually AC-powered, that consists of glass or plastic fibers which have special optical properties. The device is usually attached to a dental handpiece and is intended to illuminate a patient's oral structures.

(b) *Classification.* Class I.

6. Section 872.6250 is added to Subpart G to read as follows:

§ 872.6250 Dental chair and accessories.

(a) *Identification.* A dental chair and accessories is a device, usually AC-powered, in which a patient sits. The device is intended to properly position a patient to perform dental procedures. A dental operative unit may be attached.

(b) *Classification.* Class I.

7. Section 872.6475 is added to Subpart G to read as follows:

§ 872.6475 Heat source for bleaching teeth.

(a) *Identification.* A heat source for bleaching teeth is an AC-powered device that consists of a light or an electric heater intended to apply heat to a tooth after it is treated with a bleaching agent.

(b) *Classification.* Class I.

8. Section 872.6510 is added to Subpart G to read as follows:

§ 872.6510 Oral irrigation unit.

(a) *Identification.* An oral irrigation unit is an AC-powered device intended to provide a pressurized stream of water to remove food particles from between the teeth and promote good periodontal (gum) condition.

(b) *Classification.* Class I.

9. Section 872.6640 is added to Subpart G to read as follows:

§ 872.6640 Dental operative unit and accessories.

(a) *Identification.* A dental operative unit and accessories is an AC-powered device that is intended to supply power to and serve as a base for other dental devices, such as a dental handpiece, a dental operating light, an air or water syringe unit, an oral cavity evacuator, a suction operative unit, and other dental devices and accessories. The device may be attached to a dental chair.

(b) *Classification.* Class I.

10. Section 872.6710 is added to Subpart G to read as follows:

§ 872.6710 Boiling water sterilizer.

(a) *Identification.* A boiling water sterilizer is an AC-powered device that consists of a container for boiling water. The device is intended to sterilize dental and surgical instruments by submersion in the boiling water in the container.

(b) *Classification.* Class I.

11. Section 872.6865 is added to Subpart G to read as follows:

§ 872.6865 Powered toothbrush.

(a) *Identification.* A powered toothbrush is an AC-powered or battery powered device that consists of a handle containing a motor that provides mechanical vibrations to the shaft of a manual toothbrush inserted in one end. The device is intended to remove adherent plaque and food debris from the teeth to reduce tooth decay.

(b) *Classification.* Class I.

PART 874—EAR, NOSE, AND THROAT DEVICES

12. The authority citation for 21 CFR Part 874 continues to read as follows:

Authority: Secs. 501(f), 510, 513, 515, 520, 701(a), 52 Stat. 1055, 76 Stat. 794–795 as amended, 90 Stat, 540–546, 552–559, 565–574, 576–577 (21 U.S.C. 351(f), 360, 360c, 360e, 360j, 371(a)); 21 CFR 5.10.

13. Section 874.1070 is added to Subpart B to read as follows:

§ 874.1070 Short increment sensitivity index (SISI) adapter.

(a) *Identification.* A short increment sensitivity index (SISI) adapter is a device used with an audiometer in diagnostic hearing evaluations. A SISI adapter provides short periodic sound pulses in specific small decibel increments that are intended to be superimposed on the audiometer's output tone frequency.

(b) *Classification.* Class I.

14. Section 874.1800 is added to Subpart B to read as follows:

§ 874.1800 Air or water caloric stimulator.

(a) *Identification.* An air or water caloric stimulator is a device that delivers a stream of air or water to the ear canal at controlled rates of flow and temperature and that is intended for vestibular function testing of a patient's body balance system. The vestibular stimulation of the semicircular canals produce involuntary eye movements that are measured and recorded by a nystagmograph.

(b) *Classification.* Class I.

15. Section 874.4750 is added to Subpart E to read as follows:

§ 874.4750 Laryngostroboscope.

(a) *Identification.* A laryngostroboscope is a device that is intended to allow observation of glottic action during phonation. The device operates by focusing a stroboscopic light through a lens for direct or mirror reflected viewing of glottic action. The light and microphone that amplifies accoustic signals from the glottic area may or may not contact the patient.

(b) *Classification.* Class I.

16. Section 874.4770 is added to Subpart E to read as follows:

§ 874.4770 Otoscope

(a) *Identification.* An otoscope is a device intended to allow inspection of the external ear canal and tympanic membrane under magnification. The device provides illumination of the ear canal for observation by using an AC- or battery-powered light source and an optical magnifying system.

(b) *Classification.* Class I.

17. Section 874.5300 is added to Subpart F to read as follows:

§ 874.5300 Ear, nose, and throat examination and treatment unit.

(a) *Identification.* An ear, nose, and throat examination and treatment unit is an AC-powered device intended to support a patient during an otologic examination while providing specialized features for examination and treatment. The unit consists of a patient chair and table, drawers for equipment, suction and blowing apparatus, and receptacles for connection of specialized lights and examining instruments.

(b) *Classification.* Class I.

18. Section 874.5550 is added to Subpart F to read as follows:

§ 874.5550 Powered nasal irrigator.

(a) *Identification.* A powered nasal irrigator is an AC-powered device intended to wash the nasal cavity by means of a pressure-controlled, pulsating stream of water. The device consists of a control unit and pump connected to a spray tube and nozzle.

(b) *Classification.* Class I.

PART 878—GENERAL AND PLASTIC SURGERY DEVICES

19. The authority citation for 21 CFR Part 878 continues to read as follows:

Authority: Secs. 501(f), 510, 513, 515, 520, 701(a), 52 Stat. 1055, 76 Stat. 794–795 as amended, 90 Stat. 540–546, 552–559, 565–574, 576–577 (21 U.S.C. 351 (f), 360, 360c, 360e, 360j, 371(a)); 21 CFR 5.10.

20. Section 878.4635 is added to Subpart E to read as follows:

§ 878.4635 Ultraviolet lamp for tanning.

(a) *Identification.* An ultraviolet light for tanning is a device that is a lamp (including a fixture) intended to provide ultraviolet radiation to tan the skin. See § 1040.20 of this chapter.

(b) *Classification.* Class I.

21. Section 878.4700 is added to Subpart E to read as follows:

§ 878.4700 Surgical microscope and accessories.

(a) *Identification.* A surgical microscope and accessories is an AC-powered device intended for use during surgery to provide a magnified view of the surgical field.

(b) *Classification.* Class I.

22. Section 878.4820 is added to Subpart E to read as follows:

§ 878.4820 Surgical instrument motors and accessories/attachments.

(a) *Identification.* Surgical instrument motors and accessories are AC-powered, battery powered, or air-powered devices intended for use during surgical procedures to provide power to operate various accessories or attachments to cut hard tissue or bone and soft tissue. Accessories or attachments may include a bur, chisel (osteotome), dermabrasion brush, dermatome, drill bit, hammerhead, pin driver, and saw blade.

(b) *Classification.* Class I.

23. Section 878.4960 is added to Subpart E to read as follows:

§ 878.4960 Operating tables and accessories and operating chairs and accessories.

(a) *Identification.* Operating tables and accessories and operating chairs and accessories are AC-powered or air-powered devices, usually with movable components, intended for use during diagnostic examinations or surgical procedures to support and position a patient.

(b) *Classification.* Class I.

PART 884—OBSTETRICAL AND GYNECOLOGICAL DEVICES

24. The authority citation for 21 CFR Part 884 continues to read as follows:

Authority: Secs. 501(f), 510, 513, 515, 520, 701(a), 52 Stat. 1055, 76 Stat. 794–795 as amended, 90 Stat. 540–546, 552–559, 565–574, 576–577 (21 U.S.C. 351(f), 360, 360c, 360e, 360j, 371(a)); 21 CFR 5.10.

25. Section 884.2980 is amended by adding new paragraph (a) to read as follows:

§ 884.2980 Telethermographic system.

(a) *Telethermagraphic system intended for adjunctive diagnostic screening far detection af breast cancer ar other uses*—(1) *Identification.* A telethermographic system for adjunctive diagnostic screening for detection of breast cancer or other uses is an electrically powered device with a detector that is intended to measure, without touching the patient's skin, the self-emanating infrared radiation that reveals the temperature variations of the surface of the body. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

(2) *Classification.* Class I.

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26. Section 884.2982 is amended by revising paragraph (a) to read as follows:

§ 884.2982 Liquid crystal thermographic system.

(a) *A nonelectrically pawered or an AC-powered liquid crystal thermagraphic system intended far adjunctive use in diagnastic screening far detectian af breast cancer ar other uses*—(1) *Identification.* A nonelectrically powered or an AC-powered liquid crystal thermographic system intended for use as an adjunct to physical palpation or mammography in diagnostic screening for detection of breast cancer or other uses is a nonelectrically powered or an AC-powered device applied to the skin that displays the color patterns of heat sensitive cholesteric liquid crystals that respond to temperature variations of the surface of the body. This generic type of device may include patient and equipment supports, a means to ensure thermal contact between the patient's skin and the liquid crystals, component parts, and accessories.

(2) *Classsification.* Class I.

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PART 886—OPHTHALMIC DEVICES

27. The authority citation for 21 CFR Part 886 continues to read as follows:

Authority: Secs. 501(f), 510, 513, 515, 520, 701(a), 52 Stat. 1055, 76 Stat. 794–795 as amended, 90 Stat. 540–546, 552–559, 565–574,

576–577 (21 U.S.C. 351(f), 360, 360c, 360e, 360j, 371(a)); 21 CFR 5.10.

28. Section 886.1050 is added to Subpart B to read as follows:

§ 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.

29. Section 886.1070 is added to Subpart B to read as follows:

§ 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.

30. Section 886.1090 is added to Subpart B to read as follows:

§ 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.

31. Section 886.1120 is added to Subpart B to read as follows:

§ 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 I.

32. Section 886.1140 is revised to read as follows:

§ 886.1140 Ophthalmic chair.

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

(b) *Classification.* Class I. The manual 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.

33. Section 886.1160 is added to Subpart B to read as follows:

§ 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.

34. Section 886.1250 is revised to read as follows:

§ 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° 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 retinae 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.

35. Section 886.1290 is added to Subpart B to read as follows:

§ 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 macula retina of the eye).

(b) *Classification.* Class I.

36. Section 886.1300 is added to Subpart B to read as follows:

§ 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 I.

37. Section 886.1340 is added to Subpart B to read as follows:

§ 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.

38. Section 886.1350 is revised to read as follows:

§ 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) *Classification.* Class I. The battery-powered 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.

39. Section 886.1425 is added to Subpart B to read as follows:

§ 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.

40. Section 886.1430 is added to Subpart B to read as follows:

§ 886.1430 Ophthalmic contact lens radius measuring device.

(a) *Identification.* An ophthalmic contact lens radius measuring device is an AC-powered device that is a microscope and dial gauge intended to measure the radius of a contact lens.

(b) *Classification.* Class I.

41. Section 886.1435 is added to Subpart B to read as follows:

§ 886.1435 Maxwell spot.

(a) *Identification.* A Maxwell spot is an AC-powered device that is a light source with a red and blue filter intended to test macular function.

(b) *Classification.* Class I.

42. Section 886.1450 is added to Subpart B to read as follows:

§ 886.1450 Corneal radius measuring device.

(a) *Identification.* A corneal radius measuring device is an AC-powered device intended to measure corneal size by superimposing the image of the cornea on a scale at the focal length of

the lens of a small handheld single tube penscope or eye gauge magnifier.

(b) *Classification.* Class I.

43. Section 886.1605 is revised to read as follows:

§ 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. The manual 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.

44. Section 886.1680 is added to Subpart B to read as follows:

§ 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.

45. Section 886.1690 is added to Subpart B to read as follows:

§ 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.

46. Section 886.1700 is revised to read as follows:

§ 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. The manual 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.

47. Section 886.1780 is revised to read as follows:

§ 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.* Class I. The battery-powered 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.

48. Section 886.1810 is revised to read as follows:

§ 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 the central 30° of the patient's visual field on a flat surface. This generic type of device includes projection tangent screens, target tangent screens and targets, felt tangent screens, and battery-powered stereo campimeters.

(b) *Classification.* Class I. The battery-powered 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.

49. Section 886.1860 is revised to read as follows:

§ 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. The nonpowered 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.

50. Section 886.1870 is revised to read as follows:

§ 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. The battery-powered 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.

51. Section 886.1910 is revised to read as follows:

§ 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. The battery-powered 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.

52. Section 886.1940 is added to Subpart B to read as follows:

§ 886.1940 Tonometer sterilizer.

(a) *Identification.* A tonometer sterilizer is an AC-powered device intended to sterilize by heat a tonometer (a device used to measure intraocular pressure).

(b) *Classification.* Class I.

53. Section 886.1945 is revised to read as follows:

§ 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.

54. Section 886.4070 is revised to read as follows:

§ 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.

55. Section 886.4250 is revised to read as follows:

§ 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.

56. Section 886.4335 is revised to read as follows:

§ 886.4335 Operating headlamp.

(a) *Identification.* An operating headlamp is an AC-powered or battery-powered device intended to be worn around the head of the user to provide a

light source to aid visualization during surgical, diagnostic, or therapeutic procedures.

(b) *Clossification.* Class I.

57. Section 886.4370 is revised to read as follows:

§ 886.4370 Keratome.

(a) *Identificotion.* 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) *Clossificotion.* Class I.

58. Section 886.4855 is revised to read as follows:

§ 886.4855 Ophthalmic instrument table.

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

(b) *Clossificotion.* Class I. The manual 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.

59. Section 886.5820 is added to Subpart F to read as follows:

§ 886.5820 Closed-circuit television reading system.

(a) *Identification.* A closed-circuit television reading system is a device that consists of a lens, video camera, and video monitor that is intended for use by a patient who has subnormal vision to magnify reading material.

(b) *Clossificotion.* Class I.

60. Section 886.5900 is revised to read as follows:

§ 886.5900 Electronic vision aid.

(a) *Identificotion.* 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) *Clossification.* Class I.

61. Section 886.5915 is revised to read as follows:

§ 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) *Clossificotion.* Class I. The battery-powered 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.

PART 888—ORTHOPEDIC DEVICES

62. The authority citation for 21 CFR Part 888 continues to read as follows:

Authority: Secs. 501(f), 510, 513, 515, 520, 701(a), 52 Stat. 1055, 76 Stat. 794–795 as amended, 90 Stat. 540–546, 552–559, 565–574, 576–577 (21 U.S.C. 351(f), 360, 360c, 360e, 360j, 371(a)); 21 CFR 5.10.

63. Section 888.1500 is added to Subpart B to read as follows:

§ 886.1500 Goniometer.

(a) *Identificotion.* A goniometer is an AC-powered device intended to evaluate joint function by measuring and recording ranges of motion, acceleration, or forces exerted by a joint.

(b) *Clossificotion.* Class I.

64. Section 888.5960 is added to Subpart E to read as follows:

§ 880.5960 Cast removal instrument.

(a) *Identificotion.* A cast removal instrument is an AC-powered hand-held device intended to remove a cast from a patient. This generic type of device includes the electric cast cutter and cast vacuum.

(b) *Clossificotion.* Class I.

PART 892—RADIOLOGY DEVICES

65. The authority citation for 21 CFR Part 892 continues to read as follows:

Authority: Secs. 501(f), 510, 513, 515, 520, 701(a), 52 Stat. 1055, 76 Stat. 794–795 as amended, 90 Stat. 540–546, 552–559, 565–574, 576–577 (21 U.S.C. 351(f), 360, 360c, 360e, 360j, 371(a)); 21 CFR 5.10.

66. Section 892.1100 is added to Subpart B to read as follows:

§ 892.1100 Scintillation (gamma) camera.

(a) *Identificotion.* A scintillation (gamma) camera is a device intended to image the distribution of radionuclides in the body by means of a photon radiation detector. This generic type of device may include signal analysis and display equipment, patient and equipment supports, radionuclide anatomical markers, component parts, and accessories.

(b) *Clossification.* Class I.

67. Section 892.1110 is added to Subpart B to read as follows:

§ 892.1110 Positron camera.

(a) *Identificotion.* A positron camera is a device intended to image the distribution of positron-emitting radionuclides in the body. This generic type of a device may include signal analysis and display equipment, patient and equipment supports, radionuclide anatomical markers, component parts, and accessories.

(b) *Clossificotion.* Class I.

68. Section 892.1130 is added to Subpart B to read as follows:

§ 892.1130 Nuclear whole body counter.

(a) *Identificotion.* A nuclear whole body counter is a device intended to measure the amount of radionuclides in the entire body. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

(b) *Clossificotion.* Class I.

69. Section 892.1300 is added to Subpart B to read as follows:

§ 892.1300 Nuclear rectilinear scanner.

(a) *Identificotion.* A nuclear rectilinear scanner is a device intended to image the distribution of radionuclides in the body by means of a detector (or detectors) whose position moves in two directions with respect to the patient. This generic type of device may include signal analysis and display equipment, patient and equipment supports, radionuclide anatomical markers, component parts, and accessories.

(b) *Clossification.* Class I.

70. Section 892.1320 is added to Subpart B to read as follows:

§ 892.1320 Nuclear uptake probe.

(a) *Identificotion.* A nuclear uptake probe is a device intended to measure the amount of radionuclide taken up by a particular organ or body region. This generic type of device may include a single or multiple detector probe, signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

(b) *Clossificotion.* Class I.

71. Section 892.1330 is added to Subpart B to read as follows:

§ 892.1330 Nuclear whole body scanner.

(a) *Identificotion.* A nuclear whole body scanner is a device intended to measure and image the distribution of radionuclides in the body by means of a wide-aperture detector whose position moves in one direction with respect to the patient. This generic type of device may include signal analysis and display equipment, patient and equipment supports, radionuclide anatomical markers, component parts, and accessories.

(b) *Clossification.* Class I.

72. Section 892.1350 is added to Subpart B to read as follows:

§ 892.1350 Nuclear scanning bed.

(a) *Identification.* A nuclear scanning bed is an adjustable bed intended to support a patient during a nuclear medicine procedure.

(b) *Classification.* Class I.

73. Section 892.1410 is added to Subpart B to read as follows:

§ 892.1410 Nuclear electrocardiograph synchronizer.

(a) *Identification.* A nuclear electrocardiograph synchronizer is a device intended for use in nuclear radiology to relate the time of image formation to the cardiac cycle during the production of dynamic cardiac images.

(b) *Classification.* Class I.

74. Section 892.1640 is added to Subpart B to read as follows:

§ 892.1640 Radiographic film marking system.

(a) *Identification.* A radiographic film marking system is a device intended for medical purposes to add identification and other information onto radiographic film by means of exposure to visible light.

(b) *Classification.* Class I.

75. Section 892.1890 is added to Subpart B to read as follows:

§ 892.1890 Radiographic film illuminator.

(a) *Identification.* A radiographic film illuminator is a device containing a visible light source covered with a translucent front that is intended to be used to view medical radiographs.

(b) *Classification.* Class I.

76. Section 892.1900 is added to Subpart B to read as follows:

§ 892.1900 Automatic radiographic film processor.

(a) *Identification.* An automatic radiographic film processor is a device intended to be used to develop, fix, wash, and dry automatically and continuously film exposed for medical purposes.

(b) *Classification.* Class I.

77. Section 892.1970 is added to Subpart B to read as follows:

§ 892.1970 Radiographic ECG/respirator synchronizer.

(a) *Identification.* A radiographic ECG/respirator synchronizer is a device intended to be used to coordinate an x-ray film exposure with the signal from an electrocardiograph (ECG) or respirator at a predetermined phase of the cardiac or respiratory cycle.

(b) *Classification.* Class I.

Dated: October 18, 1988.

Frank E. Young,

Commissioner of Food and Drugs.

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