

§ 880.6991

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§ 880.6991 Medical washer.

(a) *Identification.* A medical washer is a device that is intended for general medical purposes to clean and dry surgical instruments, anesthesia equipment, hollowware, and other medical devices.

(b) *Classification.* Class II (special controls). The special control for this device is the FDA guidance document entitled “Class II Special Controls Guidance Document: Medical Washers and Medical Washer-Disinfectors.” The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 880.9.

[67 FR 69121, Nov. 15, 2002]

§ 880.6992 Medical washer-disinfector.

(a) *Identification.* A medical washer-disinfector is a device that is intended for general medical purposes to clean, decontaminate, disinfect, and dry surgical instruments, anesthesia equipment, hollowware, and other medical devices.

(b) *Classification.* Class II (special controls). The special control for this device is the FDA guidance document entitled “Class II Special Controls Guidance Document: Medical Washers and Medical Washer-Disinfectors.”

(1) Medical washer-disinfectors that are intended to clean, high level disinfect, and dry surgical instruments, anesthesia equipment, hollowware, and other medical devices.

(2) Medical washer-disinfectors that are intended to clean, low or intermediate level disinfect, and dry surgical instruments, anesthesia equipment, hollowware, and other medical devices are exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 880.9.

[67 FR 69121, Nov. 15, 2002]

PART 882—NEUROLOGICAL DEVICES

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

SOURCE: 44 FR 51730, Sept. 4, 1979, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to part 882 appear at 73 FR 35341, June 23, 2008.

Subpart A—General Provisions**§ 882.1 Scope.**

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

(b) The identification of a device in a regulation in this part is not a precise description of every device that is, or will be, subject to the regulation. A manufacturer who submits a pre-market notification submission for a device under part 807 may not show merely that the device is accurately described by the section title and identification provisions of a regulation in

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this part, but shall state why the device is substantially equivalent to other devices, as required by § 807.87.

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

(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>.

[52 FR 17739, May 11, 1987, as amended at 68 FR 70436, Dec. 18, 2003; 78 FR 18233, Mar. 26, 2013]

§ 882.3 Effective dates of requirement for premarket approval.

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

(a) Before FDA requires that a device commercially distributed before the enactment date of the amendments, or a device that has been found substantially equivalent to such a device, has an approval under section 515 of the act FDA must promulgate a regulation under section 515(b) of the act requiring such approval, except as provided in paragraph (b) of this section. Such a regulation under section 515(b) of the act shall not be effective during the grace period ending on the 90th day after its promulgation or on the last day of the 30th full calendar month after the regulation that classifies the device into class III is effective, whichever is later. See section 501(f)(2)(B) of the act. Accordingly, unless an effective date of the requirement for premarket approval is shown in the regu-

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lation 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.

[52 FR 17739, May 11, 1987]

§ 882.9 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 2319, Jan. 14, 2000]

Subpart B—Neurological Diagnostic Devices

§ 882.1020 Rigidity analyzer.

(a) *Identification.* A rigidity analyzer is a device for quantifying the extent of the rigidity of a patient's limb to determine the effectiveness of drugs or other treatments.

(b) *Classification.* Class II (performance standards).

§ 882.1030 Ataxiagraph.

(a) *Identification.* An ataxiagraph is a device used to determine the extent of ataxia (failure of muscular coordination) by measuring the amount of swaying of the body when the patient is standing erect and with eyes closed.

(b) *Classification.* Class I (general controls).

[44 FR 51730, Sept. 4, 1979, as amended at 66 FR 46952, Sept. 10, 2001]

§ 882.1200 Two-point discriminator.

(a) *Identification.* A two-point discriminator is a device with points used for testing a patient's touch discrimination.

(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 § 882.9. 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 of this chapter, with respect to general requirements concerning records, and § 820.198 of this chapter, with respect to complaint files.

[44 FR 51730, Sept. 4, 1979, as amended at 54 FR 25051, June 12, 1989; 65 FR 2319, Jan. 14, 2000]

§ 882.1240 Echoencephalograph.

(a) *Identification.* An echoencephalograph is an ultrasonic scanning device (including A-scan, B-scan, and doppler systems) that uses noninvasive transducers for measuring

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intracranial interfaces and blood flow velocity to and in the head.

(b) *Classification.* Class II (performance standards).

§ 882.1275 Electroconductive media.

(a) *Identification.* Electroconductive media are the conductive creams or gels used with external electrodes to reduce the impedance (resistance to alternating current) of the contact between the electrode surface and the skin.

(b) *Classification.* Class II (performance standards).

§ 882.1310 Cortical electrode.

(a) *Identification.* A cortical electrode is an electrode which is temporarily placed on the surface of the brain for stimulating the brain or recording the brain's electrical activity.

(b) *Classification.* Class II (performance standards).

§ 882.1320 Cutaneous electrode.

(a) *Identification.* A cutaneous electrode is an electrode that is applied directly to a patient's skin either to record physiological signals (e.g., the electroencephalogram) or to apply electrical stimulation.

(b) *Classification.* Class II (performance standards).

§ 882.1330 Depth electrode.

(a) *Identification.* A depth electrode is an electrode used for temporary stimulation of, or recording electrical signals at, subsurface levels of the brain.

(b) *Classification.* Class II (performance standards).

§ 882.1340 Nasopharyngeal electrode.

(a) *Identification.* A nasopharyngeal electrode is an electrode which is temporarily placed in the nasopharyngeal region for the purpose of recording electrical activity.

(b) *Classification.* Class II (performance standards).

§ 882.1350 Needle electrode.

(a) *Identification.* A needle electrode is a device which is placed subcutaneously to stimulate or to record electrical signals.

(b) *Classification.* Class II (performance standards).

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§ 882.1400 Electroencephalograph.

(a) *Identification.* An electroencephalograph is a device used to measure and record the electrical activity of the patient's brain obtained by placing two or more electrodes on the head.

(b) *Classification.* Class II (performance standards).

§ 882.1410 Electroencephalograph electrode/lead tester.

(a) *Identification.* An electroencephalograph electrode/lead tester is a device used for testing the impedance (resistance to alternating current) of the electrode and lead system of an electroencephalograph to assure that an adequate contact is made between the electrode and the skin.

(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 § 882.9.

[44 FR 51730, Sept. 4, 1979, as amended at 61 FR 1123, Jan. 16, 1996; 66 FR 38807, July 25, 2001]

§ 882.1420 Electroencephalogram (EEG) signal spectrum analyzer.

(a) *Identification.* An electroencephalogram (EEG) signal spectrum analyzer is a device used to display the frequency content or power spectral density of the electroencephalogram (EEG) signal.

(b) *Classification.* Class I (general controls).

[44 FR 51730, Sept. 4, 1979, as amended at 66 FR 46953, Sept. 10, 2001]

§ 882.1430 Electroencephalograph test signal generator.

(a) *Identification.* An electroencephalograph test signal generator is a device used to test or calibrate an electroencephalograph.

(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 § 882.9.

[44 FR 51730, Sept. 4, 1979, as amended at 59 FR 63011, Dec. 7, 1994; 66 FR 38807, July 25, 2001]

§ 882.1440 Neuropsychiatric interpretive electroencephalograph assessment aid.

(a) *Identification.* The neuropsychiatric interpretive electroencephalograph assessment aid is a prescription device that uses a patient's electroencephalograph (EEG) to provide an interpretation of the patient's neuropsychiatric condition. The neuropsychiatric interpretive EEG assessment aid is used only as an assessment aid for a medical condition for which there exists other valid methods of diagnosis.

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

(1) The technical parameters of the device, hardware and software, must be fully characterized and must demonstrate a reasonable assurance of safety and effectiveness.

(i) Hardware specifications must be provided. Appropriate verification, validation, and hazard analysis must be performed.

(ii) Software, including any proprietary algorithm(s) used by the device to arrive at its interpretation of the patient's condition, must be described in detail in the software requirements specification and software design specification. Appropriate software verification, validation, and hazard analysis must be performed.

(2) The device parts that contact the patient must be demonstrated to be biocompatible.

(3) The device must be designed and tested for electrical safety, electromagnetic compatibility, thermal, and mechanical safety.

(4) Clinical performance testing must demonstrate the accuracy, precision, reproducibility, of determining the EEG-based interpretation, including any specified equivocal zones (cutoffs).

(5) Clinical performance testing must demonstrate the ability of the device to function as an assessment aid for the medical condition for which the device is indicated. Performance measures must demonstrate device performance characteristics per the intended use in the intended use environment. Performance measurements must include sensitivity, specificity, positive predictive value, and negative pre-

dictive value per the device intended use. Repeatability of measurements must be demonstrated using interclass correlation coefficients and illustrated by qualitative scatter plot(s).

(6) The device design must include safeguards to prevent use of the device as a stand-alone diagnostic.

(7) The labeling must include the following information:

(i) A warning that the device is not to be used as a stand-alone diagnostic.

(ii) A detailed summary of the clinical performance testing, including any adverse events and complications.

(iii) The qualifications and training requirements for device users including technicians and clinicians.

(iv) The intended use population and the intended use environment.

(v) Any instructions technicians should convey to patients regarding the collection of EEG data.

(vi) Information allowing clinicians to gauge clinical risk associated with integrating the EEG interpretive assessment aid into their diagnostic pathway.

(vii) Where appropriate, validated methods and instructions for reprocessing of any reusable components.

[79 FR 9085, Feb. 18, 2014]

§ 882.1450 Brain injury adjunctive interpretive electroencephalograph assessment aid.

(a) *Identification.* A brain injury adjunctive interpretive electroencephalograph assessment aid is a prescription device that uses a patient's electroencephalograph (EEG) to provide an interpretation of the structural condition of the patient's brain in the setting of trauma. A brain injury adjunctive interpretive EEG assessment aid is for use as an adjunct to standard clinical practice only as an assessment aid for a medical condition for which there exists other valid methods of diagnosis.

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

(1) The technical parameters of the device, hardware and software, must be fully characterized and include the following information:

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(i) Hardware specifications must be provided. Appropriate verification, validation, and hazard analysis must be performed.

(ii) Software, including any proprietary algorithm(s) used by the device to arrive at its interpretation of the patient's condition, must be described in detail in the software requirements specification (SRS) and software design specification (SDS). Appropriate software verification, validation, and hazard analysis must be performed.

(2) The device parts that contact the patient must be demonstrated to be biocompatible.

(3) The device must be designed and tested for electrical safety, electromagnetic compatibility (EMC), thermal, and mechanical safety.

(4) Clinical performance testing must demonstrate the accuracy, precision, repeatability and reproducibility, of determining the EEG-based interpretation, including any specified equivocal zones (cutoffs).

(5) Clinical performance testing must demonstrate the ability of the device to function as an assessment aid for the medical condition for which the device is indicated. Performance measures must demonstrate device performance characteristics per the intended use in the intended use environment. Performance measurements must include sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) with respect to the study prevalence per the device intended use.

(6) The device design must include safeguards to ensure appropriate clinical interpretation of the device output (*e.g.*, use in appropriate patient population, or for appropriate clinical decision).

(7) The labeling and training information must include:

(i) A warning that the device is not to be used as a stand-alone diagnostic.

(ii) A detailed summary of the clinical performance testing, including any adverse events and complications.

(iii) The intended use population and the intended use environment.

(iv) Any instructions technicians should convey to patients regarding the collection of EEG data.

(v) Information allowing clinicians to gauge clinical risk associated with integrating the EEG interpretive assessment aid into their diagnostic pathway.

(vi) Information allowing clinicians to understand how to integrate the device output into their diagnostic pathway when the device is unable to provide a classification or final result.

[80 FR 16268, Mar. 27, 2015]

§ 882.1460 Nystagmograph.

(a) *Identification.* A nystagmograph is a device used to measure, record, or visually display the involuntary movements (nystagmus) of the eyeball.

(b) *Classification.* Class II (performance standards).

§ 882.1480 Neurological endoscope.

(a) *Identification.* A neurological endoscope is an instrument with a light source used to view the inside of the ventricles of the brain.

(b) *Classification.* Class II (performance standards).

§ 882.1500 Esthesiometer.

(a) *Identification.* An esthesiometer is a mechanical device which usually consists of a single rod or fiber which is held in the fingers of the physician or other examiner and which is used to determine whether a patient has tactile 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 § 882.9. 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 of this chapter, with respect to general requirements concerning records, and § 820.198 of this chapter, with respect to complaint files.

[44 FR 51730, Sept. 4, 1979, as amended at 54 FR 25051, June 12, 1989; 65 FR 2319, Jan. 14, 2000]

§ 882.1525 Tuning fork.

(a) *Identification.* A tuning fork is a mechanical device which resonates at a given frequency and is used to diagnose

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hearing disorders and to test for vibratory sense.

(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 § 882.9. The device is also exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, 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 FR 51730, Sept. 4, 1979, as amended at 54 FR 25051, June 12, 1989; 66 FR 38807, July 25, 2001]

§ 882.1540 Galvanic skin response measurement device.

(a) *Identification.* A galvanic skin response measurement device is a device used to determine autonomic responses as psychological indicators by measuring the electrical resistance of the skin and the tissue path between two electrodes applied to the skin.

(b) *Classification.* Class II (performance standards).

§ 882.1550 Nerve conduction velocity measurement device.

(a) *Identification.* A nerve conduction velocity measurement device is a device which measures nerve conduction time by applying a stimulus, usually to a patient's peripheral nerve. This device includes the stimulator and the electronic processing equipment for measuring and displaying the nerve conduction time.

(b) *Classification.* Class II (performance standards).

§ 882.1560 Skin potential measurement device.

(a) *Identification.* A skin potential measurement device is a general diagnostic device used to measure skin voltage by means of surface skin electrodes.

(b) *Classification.* Class II (performance standards).

§ 882.1570 Powered direct-contact temperature measurement device.

(a) *Identification.* A powered direct-contact temperature measurement de-

vice is a device which contains a power source and is used to measure differences in temperature between two points on the body.

(b) *Classification.* Class II (performance standards).

§ 882.1610 Alpha monitor.

(a) *Identification.* An alpha monitor is a device with electrodes that are placed on a patient's scalp to monitor that portion of the electroencephalogram which is referred to as the alpha wave.

(b) *Classification.* Class II (performance standards).

§ 882.1620 Intracranial pressure monitoring device.

(a) *Identification.* An intracranial pressure monitoring device is a device used for short-term monitoring and recording of intracranial pressures and pressure trends. The device includes the transducer, monitor, and interconnecting hardware.

(b) *Classification.* Class II (performance standards).

§ 882.1700 Percussor.

(a) *Identification.* A percussor is a small hammerlike device used by a physician to provide light blows to a body part. A percussor is used as a diagnostic aid during physical examinations.

(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 § 882.9. 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.

[44 FR 51730, Sept. 4, 1979, as amended at 54 FR 25051, June 12, 1989; 59 FR 63011, Dec. 7, 1994; 66 FR 38807, July 25, 2001]

§ 882.1750 Pinwheel.

(a) *Identification.* A pinwheel is a device with sharp points on a rotating wheel used for testing pain sensation.

(b) *Classification.* Class I (general controls). The device is exempt from the

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premarket notification procedures in subpart E of part 807 of this chapter subject to § 882.9.

[44 FR 51730, Sept. 4, 1979, as amended at 54 FR 25051, June 12, 1989; 65 FR 2319, Jan. 14, 2000]

§ 882.1790 Ocular plethysmograph.

(a) *Identification.* An ocular plethysmograph is a device used to measure or detect volume changes in the eye produced by pulsations of the artery, to diagnose carotid artery occlusive disease (restrictions on blood flow in the carotid artery).

(b) *Classification.* Class III (premarket approval).

(c) Date PMA or notice of completion of PDP is required. A PMA or notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before September 21, 2004, for any ocular plethysmograph that was in commercial distribution before May 28, 1976. Any other ocular plethysmograph shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

[44 FR 51730, Sept. 4, 1979, as amended at 52 FR 17739, May 11, 1987; 69 FR 34920, June 23, 2004]

§ 882.1825 Rheoencephalograph.

(a) *Identification.* A rheoencephalograph is a device used to estimate a patient's cerebral circulation (blood flow in the brain) by electrical impedance methods with direct electrical connections to the scalp or neck area.

(b) *Classification.* Class III (premarket approval).

(c) *Date PMA or notice of completion of a PDP is required.* A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any rheoencephalograph that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to a rheoencephalograph that was in commercial distribution before May 28, 1976. Any other rheoencephalograph shall have an approved PMA or a declared completed PDP in effect before

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being placed in commercial distribution.

[44 FR 51730, Sept. 4, 1979, as amended at 52 FR 17740, May 11, 1987; 61 FR 50708, Sept. 27, 1996]

§ 882.1835 Physiological signal amplifier.

(a) *Identification.* A physiological signal amplifier is a general purpose device used to electrically amplify signals derived from various physiological sources (e.g., the electroencephalogram).

(b) *Classification.* Class II (performance standards).

§ 882.1845 Physiological signal conditioner.

(a) *Identification.* A physiological signal conditioner is a device such as an integrator or differentiator used to modify physiological signals for recording and processing.

(b) *Classification.* Class II (performance standards).

§ 882.1855 Electroencephalogram (EEG) telemetry system.

(a) *Identification.* An electroencephalogram (EEG) telemetry system consists of transmitters, receivers, and other components used for remotely monitoring or measuring EEG signals by means of radio or telephone transmission systems.

(b) *Classification.* Class II (performance standards).

§ 882.1870 Evoked response electrical stimulator.

(a) *Identification.* An evoked response electrical stimulator is a device used to apply an electrical stimulus to a patient by means of skin electrodes for the purpose of measuring the evoked response.

(b) *Classification.* Class II (performance standards).

§ 882.1880 Evoked response mechanical stimulator.

(a) *Identification.* An evoked response mechanical stimulator is a device used to produce a mechanical stimulus or a series of mechanical stimuli for the purpose of measuring a patient's evoked response.

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(b) *Classification*. Class II (performance standards).

§ 882.1890 Evoked response photic stimulator.

(a) *Identification*. An evoked response photic stimulator is a device used to generate and display a shifting pattern or to apply a brief light stimulus to a patient's eye for use in evoked response measurements or for electroencephalogram (EEG) activation.

(b) *Classification*. Class II (performance standards).

§ 882.1900 Evoked response auditory stimulator.

(a) *Identification*. An evoked response auditory stimulator is a device that produces a sound stimulus for use in evoked response measurements or electroencephalogram activation.

(b) *Classification*. Class II (performance standards).

§ 882.1925 Ultrasonic scanner calibration test block.

(a) *Identification*. An ultrasonic scanner calibration test block is a block of material with known properties used to calibrate ultrasonic scanning devices (e.g., the echoencephalograph).

(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 § 882.9.

[44 FR 51730, Sept. 4, 1979, as amended at 59 FR 63011, Dec. 7, 1994; 66 FR 38807, July 25, 2001]

§ 882.1935 Near Infrared (NIR) Brain Hematoma Detector.

(a) *Identification*. A Near Infrared (NIR) Brain Hematoma Detector is a noninvasive device that employs near-infrared spectroscopy that is intended to be used to evaluate suspected brain hematomas.

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

(1) The sale, distribution, and use of this device are restricted to prescription use in accordance with § 801.109 of this chapter;

(2) The labeling must include specific instructions and the clinical training needed for the safe use of this device;

(3) Appropriate analysis/testing should validate electromagnetic compatibility (EMC), electrical safety, and battery characteristics;

(4) Performance data should validate accuracy and precision and safety features;

(5) Any elements of the device that may contact the patient should be demonstrated to be biocompatible; and,

(6) Appropriate software verification, validation, and hazard analysis should be performed.

[77 FR 16927, Mar. 23, 2012]

§ 882.1950 Tremor transducer.

(a) *Identification*. A tremor transducer is a device used to measure the degree of tremor caused by certain diseases.

(b) *Classification*. Class II (performance standards).

Subparts C–D [Reserved]

Subpart E—Neurological Surgical Devices

§ 882.4030 Skull plate anvil.

(a) *Identification*. A skull plate anvil is a device used to form alterable skull plates in the proper shape to fit the curvature of a patient's skull.

(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 § 882.9.

[44 FR 51730, Sept. 4, 1979, as amended at 59 FR 63011, Dec. 7, 1994; 66 FR 38808, July 25, 2001]

§ 882.4060 Ventricular cannula.

(a) *Identification*. A ventricular cannula is a device used to puncture the ventricles of the brain for aspiration or for injection. This device is frequently referred to as a ventricular needle.

(b) *Classification*. Class I (general controls). When made only of surgical grade stainless steel, the device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 882.9.

[44 FR 51730, Sept. 4, 1979, as amended at 65 FR 2319, Jan. 14, 2000]

§ 882.4100

§ 882.4100 Ventricular catheter.

(a) *Identification.* A ventricular catheter is a device used to gain access to the cavities of the brain for injection of material into, or removal of material from, the brain.

(b) *Classification.* Class II (performance standards).

§ 882.4125 Neurosurgical chair.

(a) *Identification.* A neurosurgical chair is an operating room chair used to position and support a patient during neurosurgery.

(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 § 882.9.

[44 FR 51730, Sept. 4, 1979, as amended at 59 FR 63012, Dec. 7, 1994; 66 FR 38808, July 25, 2001]

§ 882.4150 Scalp clip.

(a) *Identification.* A scalp clip is a plastic or metal clip used to stop bleeding during surgery on the scalp.

(b) *Classification.* Class II (performance standards).

§ 882.4175 Aneurysm clip applier.

(a) *Identification.* An aneurysm clip applier is a device used by the surgeon for holding and applying intracranial aneurysm clips.

(b) *Classification.* Class II (performance standards).

§ 882.4190 Clip forming/cutting instrument.

(a) *Identification.* A clip forming/cutting instrument is a device used by the physician to make tissue clips from wire stock.

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

[44 FR 51730, Sept. 4, 1979, as amended at 59 FR 63012, Dec. 7, 1994]

§ 882.4200 Clip removal instrument.

(a) *Identification.* A clip removal instrument is a device used to remove surgical clips from the patient.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in

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subpart E of part 807 of this chapter subject to the limitations in § 882.9.

[44 FR 51730, Sept. 4, 1979, as amended at 59 FR 63012, Dec. 7, 1994; 66 FR 38808, July 25, 2001]

§ 882.4215 Clip rack.

(a) *Identification.* A clip rack is a device used to hold or store surgical clips during 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 § 882.9.

[44 FR 51730, Sept. 4, 1979, as amended at 54 FR 25051, June 12, 1989; 59 FR 63012, Dec. 7, 1994; 66 FR 38808, July 25, 2001]

§ 882.4250 Cryogenic surgical device.

(a) *Identification.* A cryogenic surgical device is a device used to destroy nervous tissue or produce lesions in nervous tissue by the application of extreme cold to the selected site.

(b) *Classification.* Class II (performance standards).

§ 882.4275 Dowel cutting instrument.

(a) *Identification.* A dowel cutting instrument is a device used to cut dowels of bone for bone grafting.

(b) *Classification.* Class II (performance standards).

§ 882.4300 Manual cranial drills, burrs, trephines, and their accessories

(a) *Identification.* Manual cranial drills, burrs, trephines, and their accessories are bone cutting and drilling instruments that are used without a power source on a patient's skull.

(b) *Classification.* Class II (performance standards).

§ 882.4305 Powered compound cranial drills, burrs, trephines, and their accessories.

(a) *Identification.* Powered compound cranial drills, burrs, trephines, and their accessories are bone cutting and drilling instruments used on a patient's skull. The instruments employ a clutch mechanism to disengage the tip of the instrument after penetrating the skull to prevent plunging of the tip into the brain.

(b) *Classification.* Class II (performance standards).

§ 882.4310 Powered simple cranial drills, burrs, trephines, and their accessories.

(a) *Identification.* Powered simple cranial drills, burrs, trephines, and their accessories are bone cutting and drilling instruments used on a patient's skull. The instruments are used with a power source but do not have a clutch mechanism to disengage the tip after penetrating the skull.

(b) *Classification.* Class II (performance standards).

§ 882.4325 Cranial drill handpiece (brace).

(a) *Identification.* A cranial drill handpiece (brace) is a hand holder, which is used without a power source, for drills, burrs, trephines, or other cutting tools that are used on a patient's skull.

(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 § 882.9.

[44 FR 51730, Sept. 4, 1979, as amended at 61 FR 1123, Jan. 16, 1996; 66 FR 38808, July 25, 2001]

§ 882.4360 Electric cranial drill motor.

(a) *Identification.* An electric cranial drill motor is an electrically operated power source used with removable rotating surgical cutting tools or drill bits on a patient's skull.

(b) *Classification.* Class II (performance standards).

§ 882.4370 Pneumatic cranial drill motor.

(a) *Identification.* A pneumatic cranial drill motor is a pneumatically operated power source used with removable rotating surgical cutting tools or drill bits on a patient's skull.

(b) *Classification.* Class II (performance standards).

§ 882.4400 Radiofrequency lesion generator.

(a) *Identification.* A radiofrequency lesion generator is a device used to produce lesions in the nervous system or other tissue by the direct application of radiofrequency currents to selected sites.

(b) *Classification.* Class II (performance standards).

§ 882.4440 Neurosurgical headrests.

(a) *Identification.* A neurosurgical headrest is a device used to support the patient's head during a surgical procedure.

(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 § 882.9.

[44 FR 51730, Sept. 4, 1979, as amended at 59 FR 63012, Dec. 7, 1994; 66 FR 38808, July 25, 2001]

§ 882.4460 Neurosurgical head holder (skull clamp).

(a) *Identification.* A neurosurgical head holder (skull clamp) is a device used to clamp the patient's skull to hold head and neck in a particular position during surgical procedures.

(b) *Classification.* Class II (performance standards).

§ 882.4500 Cranioplasty material forming instrument.

(a) *Identification.* A cranioplasty material forming instrument is a roller used in the preparation and forming of cranioplasty (skull repair) materials.

(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 § 882.9.

[44 FR 51730, Sept. 4, 1979, as amended at 59 FR 63012, Dec. 7, 1994; 66 FR 38808, July 25, 2001]

§ 882.4525 Microsurgical instrument.

(a) *Identification.* A microsurgical instrument is a nonpowered surgical instrument used in neurological microsurgery procedures.

(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 § 882.9.

[44 FR 51730, Sept. 4, 1979, as amended at 59 FR 63012, Dec. 7, 1994; 66 FR 38808, July 25, 2001]

§ 882.4535

§ 882.4535 Nonpowered neurosurgical instrument.

(a) *Identification.* A nonpowered neurosurgical instrument is a hand instrument or an accessory to a hand instrument used during neurosurgical procedures to cut, hold, or manipulate tissue. It includes specialized chisels, osteotomes, curettes, dissectors, elevators, forceps, gouges, hooks, surgical knives, rasps, scissors, separators, spatulas, spoons, blades, blade holders, blade breakers, probes, etc.

(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 § 882.9.

[44 FR 51730, Sept. 4, 1979, as amended at 59 FR 63012, Dec. 7, 1994; 66 FR 38808, July 25, 2001]

§ 882.4545 Shunt system implantation instrument.

(a) *Identification.* A shunt system implantation instrument is an instrument used in the implantation of cerebrospinal fluid shunts, and includes tunneling instruments for passing shunt components under the skin.

(b) *Classification.* Class I (general controls). When made only of surgical grade stainless steel, the device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 882.9.

[44 FR 51730, Sept. 4, 1979, as amended at 65 FR 2319, Jan. 14, 2000]

§ 882.4560 Stereotaxic instrument.

(a) *Identification.* A stereotaxic instrument is a device consisting of a rigid frame with a calibrated guide mechanism for precisely positioning probes or other devices within a patient's brain, spinal cord, or other part of the nervous system.

(b) *Classification.* Class II (performance standards).

§ 882.4600 Leukotome.

(a) *Identification.* A leukotome is a device used to cut sections out of the brain.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in

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subpart E of part 807 of this chapter subject to the limitations in § 882.9.

[44 FR 51730, Sept. 4, 1979, as amended at 59 FR 63012, Dec. 7, 1994; 66 FR 38808, July 25, 2001]

§ 882.4650 Neurosurgical suture needle.

(a) *Identification.* A neurosurgical suture needle is a needle used in suturing during neurosurgical procedures or in the repair of nervous 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 § 882.9.

[44 FR 51730, Sept. 4, 1979, as amended at 54 FR 25051, June 12, 1989; 65 FR 2319, Jan. 14, 2000]

§ 882.4700 Neurosurgical paddie.

(a) A neurosurgical paddie is a pad used during surgery to protect nervous tissue, absorb fluids, or stop bleeding.

(b) *Classification.* Class II (performance standards).

[44 FR 51730, Sept. 4, 1979, as amended at 69 FR 10332, Mar. 5, 2004]

§ 882.4725 Radiofrequency lesion probe.

(a) *Identification.* A radiofrequency lesion probe is a device connected to a radiofrequency (RF) lesion generator to deliver the RF energy to the site within the nervous system where a lesion is desired.

(b) *Classification.* Class II (performance standards).

§ 882.4750 Skull punch.

(a) *Identification.* A skull punch is a device used to punch holes through a patient's skull to allow fixation of cranioplasty plates or bone flaps by wire or other means.

(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 § 882.9. This exemption does not apply to powered compound cranial drills, burrs, trephines, and their accessories classified under § 882.4305.

[44 FR 51730, Sept. 4, 1979, as amended at 65 FR 2319, Jan. 14, 2000]

§ 882.4800 Self-retaining retractor for neurosurgery.

(a) *Identification.* A self-retaining retractor for neurosurgery is a self-locking device used to hold the edges of a wound open during neurosurgery.

(b) *Classification.* Class II (performance standards).

§ 882.4840 Manual rongeur.

(a) *Identification.* A manual rongeur is a manually operated instrument used for cutting or biting bone during surgery involving the skull or spinal column.

(b) *Classification.* Class II (performance standards).

§ 882.4845 Powered rongeur.

(a) *Identification.* A powered rongeur is a powered instrument used for cutting or biting bone during surgery involving the skull or spinal column.

(b) *Classification.* Class II (performance standards).

§ 882.4900 Skullplate screwdriver.

(a) *Identification.* A skullplate screwdriver is a tool used by the surgeon to fasten cranioplasty plates or skullplates to a patient's skull by screws.

(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 § 882.9.

[44 FR 51730, Sept. 4, 1979, as amended at 59 FR 63012, Dec. 7, 1994; 66 FR 38808, July 25, 2001]

Subpart F—Neurological Therapeutic Devices

§ 882.5030 Methyl methacrylate for aneurysmorrhaphy.

(a) *Identification.* Methyl methacrylate for aneurysmorrhaphy (repair of aneurysms, which are balloonlike sacs formed on blood vessels) is a self-curing acrylic used to encase and reinforce intracranial aneurysms that are not amenable to conservative management, removal, or obliteration by aneurysm clip.

(b) *Classification.* Class II (performance standards).

§ 882.5050 Biofeedback device.

(a) *Identification.* A biofeedback device is an instrument that provides a visual or auditory signal corresponding to the status of one or more of a patient's physiological parameters (e.g., brain alpha wave activity, muscle activity, skin temperature, etc.) so that the patient can control voluntarily these physiological parameters.

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter when it is a prescription battery powered device that is indicated for relaxation training and muscle reeducation and prescription use, subject to § 882.9.

[44 FR 51730, Sept. 4, 1979, as amended at 63 FR 59229, Nov. 3, 1998]

§ 882.5070 Bite block.

(a) *Identification.* A bite block is a device inserted into a patient's mouth to protect the tongue and teeth while the patient is having convulsions.

(b) *Classification.* Class II (performance standards).

§ 882.5150 Intravascular occluding catheter.

(a) *Identification.* An intravascular occluding catheter is a catheter with an inflatable or detachable balloon tip that is used to block a blood vessel to treat malformations, e.g., aneurysms (balloonlike sacs formed on blood vessels) of intracranial blood vessels.

(b) *Classification.* Class III (premarket approval).

(c) *Date PMA or notice of completion of a PDP is required.* A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any intravascular occluding catheter that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to an intravascular occluding catheter that was in commercial distribution before May 28, 1976. Any other intravascular occluding catheter shall have an approved PMA or a declared completed

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PDP in effect before being placed in commercial distribution.

[44 FR 51730, Sept. 4, 1979, as amended at 52 FR 17740, May 11, 1987; 61 FR 50708, Sept. 27, 1996]

§ 882.5175 Carotid artery clamp.

(a) *Identification.* A carotid artery clamp is a device that is surgically placed around a patient's carotid artery (the principal artery in the neck that supplies blood to the brain) and has a removable adjusting mechanism that protrudes through the skin of the patient's neck. The clamp is used to occlude the patient's carotid artery to treat intracranial aneurysms (balloonlike sacs formed on blood vessels) or other intracranial vascular malformations that are difficult to attach directly by reducing the blood pressure and blood flow to the aneurysm or malformation.

(b) *Classification.* Class II (performance standards).

§ 882.5200 Aneurysm clip.

(a) *Identification.* An aneurysm clip is a device used to occlude an intracranial aneurysm (a balloonlike sac formed on a blood vessel) to prevent it from bleeding or bursting.

(b) *Classification.* Class II (performance standards).

§ 882.5225 Implanted malleable clip.

(a) *Identification.* An implanted malleable clip is a bent wire or staple that is forcibly closed with a special instrument to occlude an intracranial blood vessel or aneurysm (a balloonlike sac formed on a blood vessel), stop bleeding, or hold tissue or a mechanical device in place in a patient.

(b) *Classification.* Class II (performance standards).

§ 882.5235 Aversive conditioning device.

(a) *Identification.* An aversive conditioning device is an instrument used to administer an electrical shock or other noxious stimulus to a patient to modify undesirable behavioral characteristics.

(b) *Classification.* Class II (performance standards).

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§ 882.5250 Burr hole cover.

(a) *Identification.* A burr hole cover is a plastic or metal device used to cover or plug holes drilled into the skull during surgery and to reattach cranial bone removed during surgery.

(b) *Classification.* Class II (performance standards).

§ 882.5275 Nerve cuff.

(a) *Identification.* A nerve cuff is a tubular silicone rubber sheath used to encase a nerve for aid in repairing the nerve (e.g., to prevent ingrowth of scar tissue) and for capping the end of the nerve to prevent the formation of neuroma (tumors).

(b) *Classification.* Class II (performance standards).

§ 882.5300 Methyl methacrylate for cranioplasty.

(a) *Identification.* Methyl methacrylate for cranioplasty (skull repair) is a self-curing acrylic that a surgeon uses to repair a skull defect in a patient. At the time of surgery, the surgeon initiates polymerization of the material and forms it into a plate or other appropriate shape to repair the defect.

(b) *Classification.* Class II (performance standards).

§ 882.5320 Preformed alterable cranioplasty plate.

(a) *Identification.* A preformed alterable cranioplasty plate is a device that is implanted into a patient to repair a skull defect. It is constructed of a material, e.g., tantalum, that can be altered or reshaped at the time of surgery without changing the chemical behavior of the material.

(b) *Classification.* Class II (performance standards).

§ 882.5330 Preformed nonalterable cranioplasty plate.

(a) *Identification.* A preformed nonalterable cranioplasty plate is a device that is implanted in a patient to repair a skull defect and is constructed of a material, e.g., stainless steel or vitallium, that cannot be altered or reshaped at the time of surgery without changing the chemical behavior of the material.

(b) *Classification.* Class II (performance standards).

§ 882.5360 Cranioplasty plate fastener.

(a) *Identification.* A cranioplasty plate fastener is a screw, wire, or other article made of tantalum, vitallium, or stainless steel used to secure a plate to the patient's skull to repair a skull defect.

(b) *Classification.* Class II (performance standards).

§ 882.5500 Lesion temperature monitor.

(a) *Identification.* A lesion temperature monitor is a device used to monitor the tissue temperature at the site where a lesion (tissue destruction) is to be made when a surgeon uses a radio-frequency (RF) lesion generator and probe.

(b) *Classification.* Class II (performance standards).

§ 882.5550 Central nervous system fluid shunt and components.

(a) *Identification.* A central nervous system fluid shunt is a device or combination of devices used to divert fluid from the brain or other part of the central nervous system to an internal delivery site or an external receptacle for the purpose of relieving elevated intracranial pressure or fluid volume (e.g., due to hydrocephalus). Components of a central nervous system shunt include catheters, valved catheters, valves, connectors, and other accessory components intended to facilitate use of the shunt or evaluation of a patient with a shunt.

(b) *Classification.* Class II (performance standards).

§ 882.5800 Cranial electrotherapy stimulator.

(a) *Identification.* A cranial electrotherapy stimulator is a device that applies electrical current to a patient's head to treat insomnia, depression, or anxiety.

(b) *Classification.* Class III (premarket approval).

(c) *Date a PMA or notice of completion of a PDP is required.* No effective date has been established of the require-

ment for premarket approval. See § 882.3.

[44 FR 51730, Sept. 4, 1979, as amended at 52 FR 17740, May 11, 1987; 60 FR 43969, Aug. 24, 1995; 62 FR 30457, June 4, 1997; 73 FR 34860, June 19, 2008]

§ 882.5805 Repetitive transcranial magnetic stimulation system.

(a) *Identification.* A repetitive transcranial magnetic stimulation system is an external device that delivers transcranial repetitive pulsed magnetic fields of sufficient magnitude to induce neural action potentials in the prefrontal cortex to treat the symptoms of major depressive disorder without inducing seizure in patients who have failed at least one antidepressant medication and are currently not on any antidepressant therapy.

(b) *Classification.* Class II (special controls). The special control is FDA's "Class II Special Controls Guidance Document: Repetitive Transcranial Magnetic Stimulation System." See § 882.1(e) for the availability of this guidance document.

[76 FR 44491, July 26, 2011]

§ 882.5808 Transcranial magnetic stimulator for headache.

(a) *Identification.* A transcranial magnetic stimulator device for headache is a device that delivers brief duration, rapidly alternating, or pulsed, magnetic fields that are externally directed at spatially discrete regions of the brain to induce electrical currents for the treatment of headache.

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

(1) Appropriate analysis/testing must demonstrate electromagnetic compatibility, electrical safety, and thermal safety.

(2) Appropriate verification, validation, and hazard analysis must be performed on the device software and firmware.

(3) The elements of the device that contact the patient must be assessed to be biocompatible.

(4) Non-clinical testing data must demonstrate that the device performs as intended under anticipated conditions of use. This includes full characterization of the magnetic pulse output

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and resulting magnetic field map. This also includes characterization of the sound level of the device during use.

(5) Clinical testing must demonstrate that the device is safe and effective for treating headache in the indicated patient population.

(6) The physician and patient labeling must include the following:

(i) A summary of the clinical performance testing, including any adverse events and complications.

(ii) The intended use population in terms of the types of headaches appropriate for use with the device.

(iii) Information on how to report adverse events and device malfunctions.

(iv) A diagram or picture depicting the proper placement of the device on the user.

[78 FR 38458, July 8, 2014]

§ 882.5810 External functional neuromuscular stimulator.

(a) *Identification.* An external functional neuromuscular stimulator is an electrical stimulator that uses external electrodes for stimulating muscles in the leg and ankle of partially paralyzed patients (e.g., after stroke) to provide flexion of the foot and thus improve the patient's gait.

(b) *Classification.* Class II (performance standards).

§ 882.5820 Implanted cerebellar stimulator.

(a) *Identification.* An implanted cerebellar stimulator is a device used to stimulate electrically a patient's cerebellar cortex for the treatment of intractable epilepsy, spasticity, and some movement disorders. The stimulator consists of an implanted receiver with electrodes that are placed on the patient's cerebellum and an external transmitter for transmitting the stimulating pulses across the patient's skin to the implanted receiver.

(b) *Classification.* Class III (premarket approval).

(c) *Date premarket approval application (PMA) or notice of completion of a product development protocol (PDP) is required.* A PMA or notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before September 26, 1984. Any implanted cerebellar stimulator that was

not in commercial distribution before May 28, 1976, or that has not on or before September 26, 1984 been found by FDA to be substantially equivalent to an implanted cerebellar stimulator that was in commercial distribution before May 28, 1976 shall have an approved PMA or declared completed PDP in effect before beginning commercial distribution.

[44 FR 51730, Sept. 4, 1979, as amended at 49 FR 26574, June 28, 1984]

§ 882.5830 Implanted diaphragmatic/phrenic nerve stimulator.

(a) *Identification.* An implanted diaphragmatic/phrenic nerve stimulator is a device that provides electrical stimulation of a patient's phrenic nerve to contract the diaphragm rhythmically and produce breathing in patients who have hypoventilation (a state in which an abnormally low amount of air enters the lungs) caused by brain stem disease, high cervical spinal cord injury, or chronic lung disease. The stimulator consists of an implanted receiver with electrodes that are placed around the patient's phrenic nerve and an external transmitter for transmitting the stimulating pulses across the patient's skin to the implanted receiver.

(b) *Classification.* Class III (premarket approval).

(c) *Date premarket approval application (PMA) or notice of completion of a product development protocol (PDP) is required.* A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before July 7, 1986 for any implanted diaphragmatic/phrenic nerve stimulator that was in commercial distribution before May 28, 1976, or that has on or before July 7, 1986 been found to be substantially equivalent to an implanted diaphragmatic/phrenic nerve stimulator that was in commercial distribution before May 28, 1976. Any other implanted diaphragmatic/phrenic nerve stimulator shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

[44 FR 51730, Sept. 4, 1979, as amended at 51 FR 12101, Apr. 8, 1986]

§ 882.5840 Implanted intracerebral/subcortical stimulator for pain relief.

(a) *Identification.* An implanted intracerebral/subcortical stimulator for pain relief is a device that applies electrical current to subsurface areas of a patient's brain to treat severe intractable pain. The stimulator consists of an implanted receiver with electrodes that are placed within a patient's brain and an external transmitter for transmitting the stimulating pulses across the patient's skin to the implanted receiver.

(b) *Classification.* Class III (premarket approval).

(c) *Date premarket approval application (PMA) or notice of completion of a product development protocol (PDP) is required.* A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before March 1, 1989, for any implanted intracerebral/subcortical stimulator for pain relief that was in commercial distribution before May 28, 1976, or that has on or before March 1, 1989, been found to be substantially equivalent to an implanted intracerebral/subcortical stimulator for pain relief that was in commercial distribution before May 28, 1976. Any other implanted intracerebral/subcortical stimulator for pain relief shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

[44 FR 51730, Sept. 4, 1979, as amended at 53 FR 48621, Dec. 1, 1988]

§ 882.5850 Implanted spinal cord stimulator for bladder evacuation.

(a) *Identification.* An implanted spinal cord stimulator for bladder evacuation is an electrical stimulator used to empty the bladder of a paraplegic patient who has a complete transection of the spinal cord and who is unable to empty his or her bladder by reflex means or by the intermittent use of catheters. The stimulator consists of an implanted receiver with electrodes that are placed on the conus medullaris portion of the patient's spinal cord and an external transmitter for transmitting the stimulating pulses across the patient's skin to the implanted receiver.

(b) *Classification.* Class III (premarket approval).

(c) *Date PMA or notice of completion of a PDP is required.* A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any implanted spinal cord stimulator for bladder evacuation that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to an implanted spinal cord stimulator for bladder evacuation that was in commercial distribution before May 28, 1976. Any other implanted spinal cord stimulator for bladder evacuation shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

[44 FR 51730, Sept. 4, 1979, as amended at 52 FR 17740, May 11, 1987; 61 FR 50708, Sept. 27, 1996]

§ 882.5860 Implanted neuromuscular stimulator.

(a) *Identification.* An implanted neuromuscular stimulator is a device that provides electrical stimulation to a patient's peroneal or femoral nerve to cause muscles in the leg to contract, thus improving the gait in a patient with a paralyzed leg. The stimulator consists of an implanted receiver with electrodes that are placed around a patient's nerve and an external transmitter for transmitting the stimulating pulses across the patient's skin to the implanted receiver. The external transmitter is activated by a switch in the heel in the patient's shoe.

(b) *Classification.* Class III (premarket approval).

(c) *Date PMA or notice of completion of PDP is required.* A PMA or notice of completion of a PDP for a device described in paragraph (b) of this section is required to be filed with the Food and Drug Administration on or before July 13, 1999 for any implanted neuromuscular stimulator that was in commercial distribution before May 28, 1976, or that has, on or before July 13, 1999, been found to be substantially equivalent to an implanted neuromuscular stimulator that was in commercial distribution before May 28,

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1976. Any other implanted neuromuscular stimulator shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

[44 FR 51730, Sept. 4, 1979, as amended at 52 FR 17740, May 11, 1987; 64 FR 18329, Apr. 14, 1999]

§ 882.5870 Implanted peripheral nerve stimulator for pain relief.

(a) *Identification.* An implanted peripheral nerve stimulator for pain relief is a device that is used to stimulate electrically a peripheral nerve in a patient to relieve severe intractable pain. The stimulator consists of an implanted receiver with electrodes that are placed around a peripheral nerve and an external transmitter for transmitting the stimulating pulses across the patient's skin to the implanted receiver.

(b) *Classification.* Class II (performance standards).

[44 FR 51730, Sept. 4, 1979, as amended at 78 FR 18234, Mar. 26, 2013]

§ 882.5880 Implanted spinal cord stimulator for pain relief.

(a) *Identification.* An implanted spinal cord stimulator for pain relief is a device that is used to stimulate electrically a patient's spinal cord to relieve severe intractable pain. The stimulator consists of an implanted receiver with electrodes that are placed on the patient's spinal cord and an external transmitter for transmitting the stimulating pulses across the patient's skin to the implanted receiver.

(b) *Classification.* Class II (performance standards).

§ 882.5890 Transcutaneous electrical nerve stimulator for pain relief.

(a) *Identification.* A transcutaneous electrical nerve stimulator for pain relief is a device used to apply an electrical current to electrodes on a patient's skin to treat pain.

(b) *Classification.* Class II (performance standards).

§ 882.5891 Transcutaneous electrical nerve stimulator to treat headache.

(a) *Identification.* A transcutaneous electrical nerve stimulator to treat headache is a device used to apply an

electrical current to a patient's cranium through electrodes placed on the skin.

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

(1) The patient-contacting components of the device must be demonstrated to be biocompatible.

(2) Appropriate analysis/testing must validate electromagnetic compatibility and electrical, mechanical, and thermal safety.

(3) The technical parameters of the device, including waveform, output modes, maximum output voltage and current (with 500, 2,000, and 10,000 ohm loads), pulse duration, frequency, net charge (μC) per pulse, maximum phase charge at 500 ohms, maximum current density (mA/cm^2 , r.m.s.), maximum average current (mA), maximum average power density (W/cm^2), and the type of impedance monitoring system must be fully characterized.

(4) Electrical performance, adhesive integrity, shelf life, reusability, and current distribution testing of the electrodes must be conducted.

(5) Appropriate software verification, validation, and hazard analysis must be performed.

(6) Clinical performance data must demonstrate that the device is safe and effective as a treatment for headache in the indicated patient population.

(7) Labeling must include the following:

(i) Appropriate contraindications such as not for use in subjects with an implanted metallic or electronic device in the head, a cardiac pacemaker, or an implanted or wearable defibrillator.

(ii) Appropriate warnings such as not to apply the device on the neck or chest, not to use the device in the presence of electronic monitoring equipment, not to use in the bath or shower, not to use while sleeping, not to use while driving, not to use while operating machinery.

(iii) Appropriate precautions such as the long-term effects of chronic use of the device are unknown.

(iv) A summary of the expected risks and benefits of using the device.

(v) A summary of the clinical performance data, including information on the patient population for which the

device has and has not been demonstrated to be effective, and any adverse events and complications.

(vi) Information on how the device operates and the typical sensations experienced during treatment.

(vii) A detailed summary of the device technical parameters.

(viii) An expiration date/shelf life for the electrodes and the number of times they can be reused.

(ix) Disposal instructions.

[79 FR 37948, July 3, 2014]

§ 882.5894 Limited output transcutaneous piezoelectric stimulator for skin reactions associated with insect bites.

(a) *Identification.* A limited output transcutaneous piezoelectric stimulator for skin reactions associated with insect bites is a device intended to alleviate skin reactions associated with insect bites via cutaneous, piezoelectric stimulation at the local site of the bite.

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

(1) Appropriate testing to characterize the electrical output specifications of the device (*i.e.*, total charge delivered, maximum instantaneous output current, maximum instantaneous output voltage, pulse duration, charge density) must be conducted.

(2) Mechanical bench testing must demonstrate that the device will withstand the labeled number duration of uses.

(3) All elements of the device that may contact the patient must be assessed to be biocompatible.

(4) Labeling must include:

(i) Validated instructions which addresses the following:

(A) Identification of areas of the body which are appropriate and not appropriate for contact with the device.

(B) Whether use of the device in conjunction with flammable materials (*e.g.*, insect repellent) is appropriate.

(C) Use of the device on or near implanted devices.

(D) How to identify the correct type of skin condition.

(ii) Technical parameters of the device (maximum output voltage (instantaneous), maximum output current (instantaneous), and pulse duration).

(iii) Language to direct end users to contact the device manufacturer and MedWatch if they experience any adverse events with this device.

(iv) The anticipated number of device uses prior to failure.

[80 FR 15165, Mar. 23, 2015]

§ 882.5900 Preformed craniostomosis strip.

(a) *Identification.* A preformed craniostomosis strip is a plastic strip used to cover bone edges of craniectomy sites (sites where the skull has been cut) to prevent the bone from regrowing in patients whose skull sutures are abnormally fused together.

(b) *Classification.* Class II (performance standards).

§ 882.5910 Dura substitute.

(a) *Identification.* A dura substitute is a sheet or material that is used to repair the dura mater (the membrane surrounding the brain).

(b) *Classification.* Class II (performance standards).

§ 882.5940 Electroconvulsive therapy device.

(a) *Identification.* An electroconvulsive therapy device is a device used for treating severe psychiatric disturbances (*e.g.*, severe depression) by inducing in the patient a major motor seizure by applying a brief intense electrical current to the patient's head.

(b) *Classification.* Class III (premarket approval).

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 882.3.

[44 FR 51730, Sept. 4, 1979, as amended at 52 FR 17740, May 11, 1987]

§ 882.5950 Neurovascular embolization device.

(a) *Identification.* A neurovascular embolization device is an intravascular implant intended to permanently occlude blood flow to cerebral aneurysms and cerebral arteriovenous malformations. This does not include cyanoacrylates and other embolic

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agents, which act by polymerization or precipitation. Embolization devices used in other vascular applications are also not included in this classification, see § 870.3300.

(b) *Classification.* Class II (special controls.) The special control for this device is the FDA guidance document entitled “Class II Special Controls Guidance Document: Vascular and Neurovascular Embolization Devices.” For availability of this guidance document, see § 882.1(e).

[69 FR 77900, Dec. 29, 2004]

§ 882.5960 Skull tongs for traction.

(a) *Identification.* Skull tongs for traction is an instrument used to immobilize a patient with a cervical spine injury (e.g., fracture or dislocation). The device is caliper shaped with tips that penetrate the skin. It is anchored to the skull and has a heavy weight attached to it that maintains, by traction, the patient’s position.

(b) *Classification.* Class II (performance standards).

§ 882.5970 Cranial orthosis.

(a) *Identification.* A cranial orthosis is a device that is intended for medical purposes to apply pressure to prominent regions of an infant’s cranium in order to improve cranial symmetry and/or shape in infants from 3 to 18 months of age, with moderate to severe nonsynostotic positional plagiocephaly, including infants with plagiocephalic-, brachycephalic-, and scaphocephalic-shaped heads.

(b) *Classification.* Class II (special controls) (prescription use in accordance with § 801.109 of this chapter, biocompatibility testing, and labeling (contraindications, warnings, precautions, adverse events, instructions for physicians and parents)).

[63 FR 40651, July 30, 1998]

§ 882.5975 Human dura mater.

(a) *Identification.* Human dura mater is human pachymeninx tissue intended to repair defects in human dura mater.

(b) *Classification.* Class II (special controls). The special control for this device is the FDA guidance document entitled “Class II Special Controls Guidance Document: Human Dura

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Mater.” See § 882.1(e) for the availability of this guidance.

(c) *Scope.* The classification set forth in this section is only applicable to human dura mater recovered prior to May 25, 2005.

[68 FR 70436, Dec. 18, 2003, as amended at 76 FR 36993, June 24, 2011]

PART 884—OBSTETRICAL AND GYNECOLOGICAL DEVICES

Subpart A—General Provisions

Sec.

884.1 Scope.

884.3 Effective dates of requirement for pre-market approval.

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

Subpart B—Obstetrical and Gynecological Diagnostic Devices

884.1040 Viscometer for cervical mucus.

884.1050 Endocervical aspirator.

884.1060 Endometrial aspirator.

884.1100 Endometrial brush.

884.1175 Endometrial suction curette and accessories.

884.1185 Endometrial washer.

884.1300 Uterotubal carbon dioxide insufflator and accessories.

884.1425 Perineometer.

884.1550 Amniotic fluid sampler (amniocentesis tray).

884.1560 Fetal blood sampler.

884.1600 Transabdominal amnioscope (fetoscope) and accessories.

884.1630 Colposcope.

884.1640 Culdoscope and accessories.

884.1660 Transcervical endoscope (amnioscope) and accessories.

884.1690 Hysteroscope and accessories.

884.1700 Hysteroscopic insufflator.

884.1720 Gynecologic laparoscope and accessories.

884.1730 Laparoscopic insufflator.

Subpart C—Obstetrical and Gynecological Monitoring Devices

884.2050 Obstetric data analyzer.

884.2225 Obstetric-gynecologic ultrasonic imager.

884.2600 Fetal cardiac monitor.

884.2620 Fetal electroencephalographic monitor.

884.2640 Fetal phonocardiographic monitor and accessories.

884.2660 Fetal ultrasonic monitor and accessories.

884.2675 Fetal scalp circular (spiral) electrode and applicator.