§ 880.6990 Infusion stand.

(a) *Identification.* The infusion stand is a stationary or movable stand intended to hold infusion liquids, infusion accessories, and other medical devices.

(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 § 880.9.

[63 FR 59718, Nov. 5, 1998]

§ 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

Subpart A—General Provisions

Sec.

Subpart B—Neurological Diagnostic Devices

Subparts C–D [Reserved]

Subpart E—Neurological Surgical Devices

Subpart F—Neurological Therapeutic Devices

AUTHORITY: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360*l*, 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 premarket 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 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 regulation for a device classified into class

III in this part, the device may be commercially distributed without FDA's issuance of an order approving a PMA or declaring completed a PDP for the device. If FDA promulgates a regulation under section 515(b) of the act requiring premarket approval for a device, section, 501(f)(1)(A) of the act applies to the device.

(b) Any new, not substantially equivalent, device introduced into commercial distribution on or after May 28, 1976, including a device formerly marketed that has been substantially altered, is classified by statute (section 513(f) of the act) into class III without any grace period and FDA must have issued an order approving a PMA or declaring completed a PDP for the device before the device is commercially distributed unless it is reclassified. If FDA knows that a device being commercially distributed may be a ''new'' device as defined in this section because of any new intended use or other reasons, FDA may codify the statutory classification of the device into class III for such new use. Accordingly, the regulation for such a class III device states that as of the enactment date of the amendments, May 28, 1976, the device must have an approval under section 515 of the act before commercial distribution.

[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 (special 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 84 FR 71815, Dec. 30, 2019]

§ 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). Except when the device is intended to provide an interpretation or a clinical implication of the measurement, it 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 66 FR 46952, Sept. 10, 2001; 84 FR 71815, Dec. 30, 2019]

§ 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 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).

§ 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 predictive 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:

(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]

§ 882.1455 Traumatic brain injury eye movement assessment aid.

(a) *Identification.* A traumatic brain injury eye movement assessment aid is a prescription device that uses a patient's tracked eye movements to provide an interpretation of the functional condition of the patient's brain. This device is an assessment aid that is not intended for standalone detection or diagnostic purposes.

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

(1) Clinical performance data under anticipated conditions of use must evaluate tracked eye movement in supporting the indications for use and include the following:

(i) Evaluation of sensitivity, specificity, positive predictive value, and negative predictive value using a reference method of diagnosis;

(ii) Evaluation of device test-retest reliability; and

(iii) A description of the development of the reference method of diagnosis, which may include a normative database, to include the following:

(A) A discussion of how the clinical work-up was completed to establish the reference method of diagnosis, including the establishment of inclusion and exclusion criteria; and

(B) If using a normative database, a description of how the ''normal'' population was established, and the statistical methods and model assumptions used.

(2) Software verification, validation, and hazard analysis must be performed. Software documentation must include a description of the algorithms used to generate device output.

(3) Performance testing must demonstrate the electrical safety and electromagnetic compatibility (EMC) of the device.

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

(5) A light hazard assessment must be performed for all eye-tracking and visual display light sources.

(6) Labeling must include:

(i) A summary of clinical performance testing conducted with the device, including sensitivity, specificity, positive predictive value, negative predictive value, and test-retest reliability;

(ii) A description of any normative database that includes the following:

(A) The clinical definition used to establish a ''normal'' population and the specific selection criteria;

(B) The format for reporting normal values;

(C) Examples of screen displays and reports generated to provide the user results and normative data;

(D) Statistical methods and model assumptions; and

(E) Any adjustments for age and gender.

(iii) A warning that the device should only be used by trained healthcare professionals;

(iv) A warning that the device does not identify the presence or absence of traumatic brain injury or other clinical diagnoses;

(v) A warning that the device is not a standalone diagnostic; and

(vi) Any instructions to convey to patients regarding the administration of the test and collection of test data.

[86 FR 71384, Dec. 16, 2021]

§ 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).

§ 882.1470 Computerized cognitive assessment aid.

(a) *Identification.* The computerized cognitive assessment aid is a prescription device that uses an individual's score(s) on a battery of cognitive tasks to provide an interpretation of the current level of cognitive function. The computerized cognitive assessment aid is used only as an assessment aid to determine level of cognitive functioning for which there exists other valid methods of cognitive assessment and does not identify the presence or absence of clinical diagnoses. The computerized cognitive assessment aid is not intended as a stand-alone or adjunctive diagnostic device.

(b) *Classification.* Class II (special controls). Except when the computerized cognitive assessment aid is intended for diagnostic assessment of specific diseases or conditions and relies on inputs from visual cues, auditory cues, and/or functional use of the hand, 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 special control(s) for this device are:

(1) The technical parameters of the device's hardware and software must be fully characterized and be accompanied by appropriate non-clinical testing:

(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 cognitive function, 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 must be designed and tested for electrical safety.

(3) The labeling must include:

(i) A summary of any testing conducted to demonstrate how the device functions as an interpretation of the current level of cognitive function. The summary of testing must include the following, if available: Any expected or observed adverse events and complications; any performance measurements including sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) per the devices intended use; a description of the repeatability of measurements; a description of how the cut-off values for categorization of measurements were determined; and a description of the construct validity of the device.

(ii) A warning that the device does not identify the presence or absence of clinical diagnoses.

(iii) A warning that the device is not a stand-alone diagnostic.

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

(v) Any instructions technicians must convey to patients regarding the administration of the test and collection of cognitive test data.

[80 FR 49138, Aug. 17, 2015, as amended at 84 FR 71815, Dec. 30, 2019]

§ 882.1471 Computerized cognitive assessment aid for concussion.

(a) *Identification.* The computerized cognitive assessment aid for concussion is a prescription device that uses an individual's score(s) on a battery of cognitive tasks to provide an indication of the current level of cognitive function in response to concussion. The computerized cognitive assessment aid for concussion is used only as an assessment aid in the management of concussion to determine cognitive function for patients after a potential concussive event where other diagnostic tools are available and does not identify the presence or absence of concussion. It is not intended as a stand-alone diagnostic device.

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

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

(2) Clinical performance data must be provided that demonstrates how the device functions as an interpretation of the current level of cognitive function

in an individual that has recently received an injury that causes concern about a possible concussion. The testing must:

(i) Evaluate device output and clinical interpretation.

(ii) Evaluate device test-retest reliability of the device output.

(iii) Evaluate construct validity of the device cognitive assessments.

(iv) Describe the construction of the normative database, which includes the following:

(A) How the clinical workup was completed to establish a ''normal'' population, including the establishment of inclusion and exclusion criteria.

(B) Statistical methods and model assumptions used.

(3) The labeling must include:

(i) A summary of any clinical testing conducted to demonstrate how the device functions as an interpretation of the current level of cognitive function in a patient that has recently received an injury that causes concern about a possible concussion. The summary of testing must include the following:

(A) Device output and clinical interpretation.

(B) Device test-retest reliability of the device output.

(C) Construct validity of the device cognitive assessments.

(D) A description of the normative database, which includes the following:

(*1*) How the clinical workup was completed to establish a ''normal'' population, including the establishment of inclusion and exclusion criteria.

(*2*) How normal values will be reported to the user.

(*3*) Representative screen shots and reports that will be generated to provide the user results and normative data.

(*4*) Statistical methods and model assumptions used.

(*5*) Whether or not the normative database was adjusted due to differences in age and gender.

(ii) A warning that the device should only be used by health care professionals who are trained in concussion management.

(iii) A warning that the device does not identify the presence or absence of concussion or other clinical diagnoses.

(iv) A warning that the device is not a stand-alone diagnostic.

(v) Any instructions technicians must convey to patients regarding the administration of the test and collection of cognitive test data.

[81 FR 87811, Dec. 6, 2016]

§ 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).

§ 882.1491 Pediatric Autism Spectrum Disorder diagnosis aid.

(a) *Identification.* A pediatric Autism Spectrum Disorder diagnosis aid is a prescription device that is intended for use as an aid in the diagnosis of Autism Spectrum Disorder in pediatric patients.

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

(1) Clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use, including an evaluation of sensitivity, specificity, positive predictive value, and negative predictive value using a reference method of diagnosis and assessment of patient behavioral symptomology.

(2) Software verification, validation, and hazard analysis must be provided. Software documentation must include a detailed, technical description of the algorithm(s) used to generate device output(s), and a cybersecurity assessment of the impact of threats and vulnerabilities on device functionality and user(s).

(3) Usability assessment must demonstrate that the intended user(s) can safely and correctly use the device.

(4) Labeling must include:

(i) Instructions for use, including a detailed description of the device, compatibility information, and information to facilitate clinical interpretation of all device outputs; and

(ii) A summary of any clinical testing conducted to demonstrate how the device functions as an interpretation of patient behavioral symptomology associated with Autism Spectrum Disorder.

The summary must include the following:

(A) A description of each device output and clinical interpretation;

(B) Any performance measures, including sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV);

(C) A description of how the cutoff values used for categorical classification of diagnoses were determined; and

(D) Any expected or observed adverse events and complications.

(iii) A statement that the device is not intended for use as a stand-alone diagnostic.

[87 FR 80445, Dec. 30, 2022]

§ 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 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 (special 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 84 FR 71815, Dec. 30, 2019]

§ 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 (special 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 84 FR 71815, Dec. 30, 2019]

§ 882.1561 Evoked photon image capture device.

(a) *Identification.* An evoked photon image capture device is a prescription,

electrically powered device intended for use as a noninvasive measurement tool that applies electricity to detect electrophysiological signals emanating from the skin, which are reported numerically and as images without clinical interpretation. The device is not intended for diagnostic purposes.

(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.

[81 FR 67155, Sept. 30, 2016]

§ 882.1570 Powered direct-contact temperature measurement device.

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

§ 882.1580 Non-electroencephalogram (EEG) physiological signal based seizure monitoring system.

(a) *Identification*. A non-electroencephalogram (non-EEG) physiological signal based seizure monitoring system is a noninvasive prescription device that collects physiological signals other than EEG to identify physiological signals that may be associated with a seizure.

(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:

(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 achieve its intended use, 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 patient-contacting components of the device must be demonstrated to be biocompatible.

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

(4) Clinical performance testing must demonstrate the ability of the device to function as an assessment aid for monitoring for seizure-related activity in the intended population and for the intended use setting. Performance measurements must include positive percent agreement and false alarm rate.

(5) Training must be provided for intended users that includes information regarding the proper use of the device and factors that may affect the collection of the physiologic data.

(6) The labeling must include health care professional labeling and patient-caregiver labeling. The health care professional and the patient-caregiver labeling must include the following information:

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

(ii) Any instructions technicians and clinicians should convey to patients and caregivers regarding the proper use of the device and factors that may affect the collection of the physiologic data.

(iii) Instructions to technicians and clinicians regarding how to set the device threshold to achieve the intended performance of the device.

[82 FR 50082, Oct. 30, 2017]

§ 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).

§ 882.1630 Cranial motion measurement device.

(a) *Identification.* A cranial motion measurement device is a prescription device that utilizes accelerometers to measure the motion or acceleration of the skull. These measurements are not to be used for diagnostic purposes.

(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:

(i) Hardware specifications must be provided. Additionally, verification and validation testing as well as a hazard analysis must be performed.

(ii) Software must be described in detail in the Software Requirements Specification (SRS) and Software Design Specification (SDS). Additionally, software verification and validation testing as well as a 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, thermal, and mechanical safety, and electromagnetic compatibility (EMC).

(4) Clinical performance testing must demonstrate the accuracy, precision, stability, and repeatability of measuring cranial motion per the intended use in the intended use environment.

(5) The labeling must include:

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

(ii) Instructions for technicians to convey to patients regarding the collection of cranial acceleration data to ensure device measurement accuracy, precision, stability, and repeatability.

(iii) Information allowing clinicians to understand potential sources of variability in the measurement to help recognize and identify changes in the measurement.

[82 FR 35071, July 28, 2017]

§ 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 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 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 (special 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 84 FR 71815, Dec. 30, 2019]

§ 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.

(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). 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 65 FR 2319, Jan. 14, 2000; 84 FR 71815, Dec. 30, 2019]

§ 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 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 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). 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 65 FR 2319, Jan. 14, 2000; 84 FR 71815, Dec. 30, 2019]

§ 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 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]

§ 882.4950 Diagnostic neurosurgical microscope filter.

(a) *Identification.* A diagnostic neurosurgical microscope filter is a device intended for use during neurosurgery to visualize fluorescence and enhance visualization of tissue associated with a specific disease or condition.

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

(1) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use, and verify and validate filter specifications and functional characteristics, including the following:

(i) Spectrum and intensity of the illumination source;

(ii) Spectrum of the excitation and emission filter modules when integrated in the surgical operating microscope;

(iii) Excitation power and power density;

(iv) Optical path loss from illumination source to objective lens or microscope camera;

(v) Homogeneity of the excitation light at the focal plane;

(vi) Fluorescence detection sensitivity;

(vii) Verification of calibration or preoperative procedures; and

(viii) If camera-based, spectral sensitivity of the camera.

(2) Labeling must include:

(i) Identification of the filter characteristics in conjunction with a compatible surgical operating microscope, to include the following:

(A) Illumination spectrum and power density; and

(B) Excitation and emission filter spectra.

(ii) Instructions for calibration or preoperative checks to ensure device functionality prior to each use;

(iii) Instructions for use with compatible surgical operating microscopes, external light sources, and cameras;

(iv) A warning that the device should only be used with fluorophores approved for use within the specified spectral ranges; and

(v) A warning that the device is not a standalone diagnostic.

[86 FR 73973, Dec. 29, 2021]

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]

§ 882.5060 Conditioning tool for eating disorders.

(a) *Identification.* A conditioning tool for eating disorders is a prescription device that non-invasively measures the mass of food eaten during a meal and provides feedback in the form of eating rate, patient satiety, and eating pattern information to the patient.

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

(1) Nonclinical performance testing must demonstrate:

(i) Device measurement accuracy and repeatability; and

(ii) Device feedback accuracy.

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

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

(4) Performance testing must demonstrate the electromagnetic compatibility (EMC) and electrical safety of the device.

(5) Labeling and patient labeling must be provided which includes the following:

(i) Information identifying and explaining how to use the device and its components; and

(ii) Information on how the device operates and the typical course of treatment.

[86 FR 68403, Dec. 2, 2021]

§ 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 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 (special controls), except for electrical stimulation devices for self-injurious or aggressive behavior. Electrical stimulation devices for self-injurious or aggressive behavior are banned. See § 895.105 of this chapter.

[44 FR 51730, Sept. 4, 1979, as amended at 85 FR 13354, Mar. 6, 2020]

§ 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 radiofrequency (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).

§ 882.5560 Cerebrospinal fluid shunt system.

(a) *Identification.* A cerebrospinal fluid shunt system is a prescription device used to monitor and 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 preventing spinal cord ischemia or injury during procedures that require reduction in central nervous system pressure. A cerebrospinal fluid shunt system may include catheters, valved catheters, valves, connectors, and pressure monitors intended to facilitate use of the shunt or evaluation of a patient with a shunt.

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

(1) The device description must include a detailed summary of the device technical parameters, including design configuration, dimensions, engineering drawings, and a list of all components with identification of their materials of construction.

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

(3) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested:

(i) Simulated use testing must be conducted to characterize fluid flow and resistance to leakage; and

(ii) Mechanical integrity testing of all connections must be conducted.

(4) Performance data must support the shelf life of the device by demonstrating continued sterility, package integrity, and device functionality over the specified shelf life.

(5) Performance data must demonstrate the sterility and pyrogenicity of patient-contacting components of the device.

(6) The labeling must include:

(i) Contraindications with respect to patients who should not receive a lumbar drain;

(ii) A warning that the device should have 24-hour-a-day availability of trained personnel to supervise monitoring and drainage;

(iii) Instructions on proper device setup, positioning, and monitoring;

(iv) Warnings and precautions to inform the user of serious hazards and special care associated with the use of the device;

(v) A statement that the device is not to be reused, reprocessed, or resterilized when open but unused; and

(vi) Cleaning instructions for the injection sites.

[86 FR 73975, Dec. 29, 2021]

§ 882.5600 Neurovascular mechanical thrombectomy device for acute ischemic stroke treatment.

(a) *Identification.* A neurovascular mechanical thrombectomy device for acute ischemic stroke treatment is a prescription device used in the treatment of acute ischemic stroke to improve clinical outcomes. The device is delivered into the neurovasculature with an endovascular approach, mechanically removes thrombus from the body, and restores blood flow in the neurovasculature.

(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) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use, including:

(i) Mechanical testing to demonstrate the device can withstand anticipated tensile, torsional, and compressive forces.

(ii) Mechanical testing to evaluate the radial forces exerted by the device.

(iii) Non-clinical testing to verify the dimensions of the device.

(iv) Non-clinical testing must demonstrate the device can be delivered to the target location in the

neurovasculature and retrieve simulated thrombus under simulated use conditions.

(v) Non-clinical testing must demonstrate the device is radiopaque and can be visualized.

(vi) Non-clinical testing must evaluate the coating integrity and particulates under simulated use conditions.

(vii) Animal testing must evaluate the safety of the device, including damage to the vessels or tissue under anticipated use conditions.

(3) Performance data must support the sterility and pyrogenicity of the patient contacting components of the device.

(4) Performance data must support the shelf-life of the device by demonstrating continued sterility, package integrity, and device functionality over the specified shelf-life.

(5) Clinical performance testing of the device must demonstrate the device performs as intended for use in the treatment of acute ischemic stroke and must capture any adverse events associated with the device and procedure.

(6) The labeling must include:

(i) Information on the specific patient population for which the device is intended for use in the treatment of acute ischemic stroke, including but not limited to, specifying time from symptom onset, vessels or location of the neurovasculature that can be accessed for treatment, and limitations on core infarct size.

(ii) Detailed instructions on proper device preparation and use for thrombus retrieval from the neurovasculature.

(iii) A summary of the clinical testing results, including a detailed summary of the device- and procedure-related complications and adverse events.

(iv) A shelf life.

[81 FR 94253, Dec. 23, 2016]

§ 882.5700 Thermal system for insomnia.

(a) *Identification.* A thermal system for insomnia is a prescription device for use in patients with insomnia that is used to apply a specified temperature to the skin surface.

(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) Performance testing must demonstrate electromagnetic compatibility and electrical safety.

(3) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be evaluated:

(i) Thermal performance of the device, including maintenance of the target temperature, must be evaluated under simulated use conditions.

(ii) Mechanical testing to demonstrate the device can withstand forces under anticipated use conditions.

(iii) Mechanical testing to demonstrate the device is resistant to leakage under anticipated use conditions.

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

(5) Patient labeling must be provided to convey information regarding safe use of the device, including instructions for assembly.

[81 FR 44772, July 11, 2016]

§ 882.5705 Digital therapy device to reduce sleep disturbance for psychiatric conditions.

(a) Identification. A digital therapy device to reduce sleep disturbance for psychiatric conditions is a prescription device that is intended to provide stimulation using a general purpose computing platform to reduce sleep disturbance in patients who experience this symptom due to psychiatric conditions such as nightmare disorder or post-traumatic stress disorder.

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

(1) Clinical performance testing under the labeled conditions for use must evaluate the following:

(i) The ability of the device to provide therapy for patients with sleep disturbance due to psychiatric conditions, using a validated measure;

(ii) Worsening of any condition-specific symptoms using a validated measure for assessment of the particular condition; and

(iii) Increase in symptoms of disturbed sleep or sleepiness using a validated measure.

(2) Software must clearly describe all features and functions of the software implementing the digital therapy. Software verification, validation, and hazard analysis must also be provided.

(3) The labeling must include the following:

(i) Patient and physician labeling must include instructions for use, including images that demonstrate how to interact with the device;

(ii) Patient and physician labeling must list the minimum operating system and general purpose computing requirements that support the software of the device;

(iii) Patient and physician labeling must include a warning that the digital therapy device is not intended for use as a stand-alone therapeutic device;

(iv) Patient and physician labeling must include a warning that the digital therapy device does not represent a substitution for the patient's medication; and

(v) Physician labeling must include a summary of the clinical performance testing conducted with the device.

[88 FR 2223, Jan. 13, 2023]

§ 882.5800 Cranial electrotherapy stimulator.

(a) *Identification.* A cranial electrotherapy stimulator is a prescription device that applies electrical current that is not intended to induce a seizure to a patient's head to treat psychiatric conditions.

(b) *Classification.* (1) Class II (special controls) when intended to treat insomnia and/or anxiety. The special controls for this device are:

(i) A detailed summary of the clinical testing pertinent to use of the device to demonstrate the effectiveness of the device to treat insomnia and/or anxiety.

(ii) Components of the device that come into human contact must be demonstrated to be biocompatible.

(iii) The device must be designed and tested for electrical safety and electromagnetic compatibility (EMC) in its intended use environment.

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

(v) The technical parameters of the device, including waveform, output mode, pulse duration, frequency, train delivery, maximum charge, and energy, must be fully characterized and verified.

(vi) The labeling for the device must include the following:

(A) The intended use population and the intended use environment;

(B) A warning that patients should be monitored by their physician for signs of worsening;

(C) A warning that instructs patients on how to mitigate the risk of headaches, and what to do should a headache occur;

(D) A warning that instructs patients on how to mitigate the risk of dizziness, and what to do should dizziness occur;

(E) A detailed summary of the clinical testing, which includes the clinical outcomes associated with the use of the device, and a summary of adverse events and complications that occurred with the device;

(F) Instructions for use that address where to place the electrodes, what stimulation parameters to use, and duration and frequency of treatment sessions. This information must be based on the results of clinical studies for the device;

(G) A detailed summary of the device technical parameters, including waveform, output mode, pulse duration, frequency, train delivery, and maximum charge and energy; and

(H) Information on validated methods for reprocessing any reusable components between uses.

(vii) Cranial electrotherapy stimulator devices marketed prior to the effective date of this reclassification must have an amendment submitted to the previously cleared premarket notification (510(k)) demonstrating compliance with these special controls.

(2) Class III (premarket approval) when intended to treat depression.

(c) Date premarket approval application (PMA) or notice of completion of 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 March 19, 2020, for any cranial electrotherapy stimulator device with an intended use described in paragraph (b)(2) of this section, that was in commercial distribution before May 28, 1976, or that has, on or before March 19, 2020, been found to be substantially equivalent to any cranial electrotherapy stimulator device with an intended use described in paragraph (b)(2) of this section, that was in commercial distribution before May 28, 1976. Any other cranial electrotherapy stimulator device with an intended use described in paragraph (b)(2) of this section shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

[84 FR 70013, Dec. 20, 2019]

§ 882.5801 Computerized behavioral therapy device for psychiatric disorders.

(a) *Identification.* A computerized behavioral therapy device for psychiatric disorders is a prescription only device intended to provide a computerized version of condition-specific behavioral therapy as an adjunct to clinician supervised outpatient treatment to patients with psychiatric conditions. The digital therapy is intended to provide patients access to therapy tools used during treatment sessions to improve recognized treatment outcomes.

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

(1) Clinical data must be provided to fulfill the following:

(i) Describe a validated model of behavioral therapy for the psychiatric disorder; and

(ii) Validate the model of behavioral therapy as implemented by the device.

(2) Software must be described in detail in the software requirements specification (SRS) and software design specification (SDS). Software verification, validation, and hazard analysis must be performed. Software documentation must demonstrate that the device effectively implements the behavioral therapy model.

(3) The following labeling must be provided:

(i) Patient and physician labeling must include instructions for use, including images that demonstrate how to interact with the device.

(ii) Patient and physician labeling must list compatible devices.

(iii) Patient and physician labeling must include a warning that the device is not intended for use as a standalone therapy.

(iv) Patient and physician labeling must include a warning that the device does not represent a substitution for the patient's medication.

(v) Physician labeling must include a summary of the clinical testing with the device.

[82 FR 61167, Dec. 27, 2017]

§ 882.5802 Transcranial magnetic stimulation system for neurological and psychiatric disorders and conditions.

(a) *Identification.* A transcranial magnetic stimulation system for neurological and psychiatric disorders and conditions is a prescription, non-implantable device that uses brief duration, rapidly alternating, or pulsed, magnetic fields to induce neural activity in the cerebral cortex. It is not intended for applying or focusing magnetic fields towards brain areas outside cerebral cortex (e.g., cerebellum). A repetitive transcranial magnetic stimulation system that is intended to treat major depressive disorder is classified in § 882.5805. A transcranial magnetic stimulation system for headache is classified in § 882.5808.

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

(1) Performance testing must demonstrate electromagnetic compatibility, electrical safety, and thermal safety.

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

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

(4) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated

conditions of use. The following performance characteristics must be tested:

(i) Magnetic pulse output testing;

(ii) Magnetic and electrical field testing;

(iii) Testing of the safety features built into the device; and

(iv) Testing of the sound levels patients are exposed to during device use.

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

(i) The risks and benefits associated with use of the device;

(ii) Detailed instructions to prevent seizures, to monitor the patient for seizure activity during treatment, and to provide seizure management care if one were to occur during treatment; and

(iii) A description of the ear protection to be worn by the patient during use of the device, including the type of protection and its noise reduction rating.

[84 FR 9230, Mar. 14, 2019]

§ 882.5803 Digital therapy device for Attention Deficit Hyperactivity Disorder.

(a) *Identification.* A digital therapy device for Attention Deficit Hyperactivity Disorder (ADHD) is a software intended to provide therapy for ADHD or any of its individual symptoms as an adjunct to clinician supervised treatment.

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

(1) Clinical performance testing must demonstrate and document the following under the labeled conditions for use, which include considerations for the ability of the device to:

(i) Use a validated measure to evaluate effectiveness of device to provide therapy for ADHD or any of its individual symptoms; and

(ii) Capture all adverse events.

(2) Software must be described and provided in a clear and detailed manner to include all features and functions of the software implementing the digital therapy. Software verification, validation, and hazard analysis must also be provided.

(3) The labeling must include the following items:

(i) Patient and physician labeling must include instructions for use, including images that demonstrate how to interact with the device;

(ii) Patient and physician labeling must list the minimum operating system (OS) requirements that support the software of the device;

(iii) Patient and physician labeling must include a warning that the digital therapy device is not intended for use as a standalone therapeutic device;

(iv) Patient and physician labeling must include a warning that the digital therapy device does not represent a substitution for the patient's medication; and

(v) Physician labeling must include a summary of the clinical performance testing conducted with the device.

[89 FR 71156, Sept. 3, 2024]

§ 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 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]

§ 882.5855 Brain stimulation programming planning software.

(a) *Identification.* The brain stimulation programming planning software is a prescription device intended to assist in planning stimulation programming for implanted brain stimulators.

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

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

(2) Usability assessment must demonstrate that the intended user(s) can safely and correctly use the device.

(3) Labeling must include:

(i) The implanted brain stimulators for which the device is compatible.

(ii) Instructions for use.

(iii) Instructions and explanations of all user-interface components.

(iv) A warning regarding use of the data with respect to not replacing clinical judgment.

[88 FR 751, Jan. 5, 2023]

§ 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, 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]

§ 882.5892 External vagal nerve stimulator for headache.

(a) *Identification.* An external vagal nerve stimulator for headache is a prescription device used to apply an electrical current to a patient's vagus nerve through electrodes placed on the skin for the treatment of headache.

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

(1) 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 shall be fully characterized through non-clinical performance testing.

(2) Software verification, validation, and hazard analysis shall be performed.

(3) Biocompatibility evaluation of the patient-contacting components of the device shall be performed.

(4) The device shall be tested for electrical, thermal, and mechanical safety, and for electromagnetic compatibility (EMC).

(5) The labeling must include:

(i) Instructions for proper use of the device, including placement of the device on the patient; and

(ii) Instructions on care and cleaning of the device.

[82 FR 61169, Dec. 27, 2017]

§ 882.5893 Thermal vestibular stimulator for headache.

(a) *Identification.* The thermal vestibular stimulator for headache is a prescription device used to stimulate the vestibular system by applying thermal waveforms through earpieces placed in a patient's ear canal for the treatment of headache.

(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) Performance testing must validate electromagnetic compatibility

and electrical, mechanical, and thermal safety.

(3) The technical parameters of the device, including waveform outputs and temperature limits, must be identified.

(4) Cleaning validation of earpieces must be conducted.

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

(6) Labeling must include the following:

(i) Information on how the device operates and the typical sensations experienced during treatment;

(ii) A detailed summary of the device's technical parameters; and

(iii) Instructions for maintenance and cleaning of the device.

[83 FR 52973, Oct. 19, 2018]

§ 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]

§ 882.5895 Vibratory counter-stimulation device.

(a) *Identification.* A vibratory counter-stimulation device is a prescription device that provides electrically powered mechanical vibration to improve the quality of sleep in patients with primary Restless Legs Syndrome.

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 882.9. The special controls for this device are:

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

(2) If the device contains software or firmware, appropriate verification, validation, and hazard analysis must be performed.

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

(4) Non-clinical testing data (including vibration frequency, amplitude, and acceleration) must demonstrate that the device performs as intended under anticipated conditions of use.

(5) Labeling must include:

(i) Specific information pertinent to use of the device by the intended patient population and the treatment regimen;

(ii) Warning to only use the device on normal, intact, clean, healthy skin;

(iii) Warning to not use the device if the user has leg skin disorders, such as eczema, psoriasis, cellulitis, non-healing wounds;

(iv) Warning to discontinue use if Restless Leg Syndrome symptoms worsen; and

(v) Instructions for end users to contact the device manufacturer and MedWatch in case they experience any adverse events when using this device.

[82 FR 13554, Mar. 14, 2017, as amended at 84 FR 71815, Dec. 30, 2019]

§ 882.5896 Percutaneous nerve stimulator for substance use disorders.

(a) *Identification.* A percutaneous nerve stimulator for substance use disorders is a device that stimulates nerves percutaneously to aid in the reduction of withdrawal symptoms associated with substance use disorders.

(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) Electromagnetic compatibility and electrical, mechanical, and thermal safety testing must be performed.

(3) Electrical performance testing of the device and electrodes must be conducted to validate the specified electrical output and duration of stimulation of the device.

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

(5) Sterility testing of the percutaneous components of the device must be performed.

(6) Shelf life testing must be performed to demonstrate continued sterility, package integrity, and device functionality over the specified shelf life.

(7) Labeling must include the following:

(i) A detailed summary of the device technical parameters;

(ii) A warning stating that the device is only for use on clean, intact skin;

(iii) Instructions for use, including placement of the device on the patient; and

(iv) A shelf life.

[83 FR 5034, Feb. 5, 2018]

§ 882.5897 External upper limb tremor stimulator.

(a) *Identification.* An external upper limb tremor stimulator is a prescription device which is placed externally on the upper limb and designed to aid in tremor symptom relief of the upper limb.

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

(1) Non-clinical performance testing must assess the following:

(i) Characterization of the electrical stimulation, including the following, must be performed: Waveforms, output modes, maximum output voltage, maximum output current, pulse duration, frequency, net charge per pulse, maximum phase charge at 500 ohms, maximum current density, maximum average current, and maximum average power density.

(ii) Impedance testing, current distribution across the electrode surface area, adhesive integrity, and shelf life testing of the electrodes and gels must be conducted.

(iii) Simulated use testing of sensor performance and the associated algorithms that determine the stimulation output must be conducted.

(2) Patient-contacting components of the device must be demonstrated to be biocompatible.

(3) Performance testing must demonstrate electrical, thermal, and mechanical safety along with electromagnetic compatibility (EMC) of the device in the intended use environment.

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

(5) Physician and patient labeling must include:

(i) Summaries of electrical stimulation parameters;

(ii) Instructions on how to correctly use and maintain the device;

(iii) Instructions and explanations of all user-interface components;

(iv) Instructions on how to clean the device;

(v) A shelf life for the electrodes and gel; and

(vi) Reuse information.

[83 FR 52316, Oct. 17, 2018]

§ 882.5898 Transcutaneous electrical nerve stimulator for attention deficit hyperactivity disorder.

(a) *Identification.* A transcutaneous electrical nerve stimulator for attention deficit hyperactivity disorder

(ADHD) is a prescription device that stimulates transcutaneously or percutaneously through electrodes placed on the forehead.

(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) Performance testing must demonstrate the electromagnetic compatibility and electrical, mechanical, and thermal safety of the device.

(3) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following must be performed:

(i) Electrical performance testing must validate electrical output and duration of stimulation;

(ii) Battery performance testing must be performed; and

(iii) Adhesive integrity testing of the electrodes must be conducted.

(4) The technical parameters of the device including waveform, maximum output current and voltage, pulse duration, frequency, net charge per pulse, maximum current density, maximum average current, and maximum average power density must be fully characterized.

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

(6) Shelf life testing of the electrodes must be performed to demonstrate continued package integrity and component functionality over the labeled shelf life.

(7) Labeling must include the following:

(i) A contraindication for patients with an implanted metallic or electronic device in the head, a cardiac pacemaker, or an implanted or wearable defibrillator;

(ii) A warning that the device is only for use on clean, intact skin;

(iii) Information on how the device operates and the typical sensations experienced during treatment;

(iv) A detailed summary of the device technical parameters;

(v) A shelf life for the electrodes;

(vi) Instructions for use, including placement of the device on the patient; and

(vii) Cleaning instructions.

[86 FR 70377, Dec. 10, 2021]

§ 882.5899 Trunk and limb electrical stimulator to treat headache.

(a) *Identification.* A trunk and limb electrical stimulator to treat headache is a device intended to treat headache through the application of electrical stimulation anywhere on the body of the patient apart from the patient's head or neck through electrodes placed on the skin. The stimulation may be provided transcutaneously or percutaneously.

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

(1) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. This testing must include:

(i) Characterization of the electrical stimulation, including the following: Waveforms; output modes; maximum output voltage and maximum output current (at 500Ω, 2kΩ, and 10kΩ loads); pulse duration; frequency; net charge per pulse; and maximum phase charge, maximum current density, maximum average current, and maximum average power density (at 500Ω);

(ii) Characterization of the impedance monitoring system; and

(iii) Characterization of the electrode performance including the electrical performance, adhesive integrity, shelf-life, reusability, and current distribution of the electrode surface area.

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

(3) Performance testing must demonstrate electromagnetic compatibility and electrical, mechanical, and thermal safety in the intended use environment.

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

(5) Labeling must include the following:

(i) Instructions for use, including the typical sensations experienced during treatment;

(ii) A detailed summary of the electrical stimulation output, and the device technical parameters, including any wireless specifications;

(iii) A shelf life for the electrodes and reuse information; and

(iv) Instructions on care and cleaning of the device.

[86 FR 68401, Dec. 2, 2021]

§ 882.5900 Preformed craniosynostosis strip.

(a) *Identification.* A preformed craniosynostosis 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 prescription device, including the pulse generator and its stimulation electrodes, used for treating severe psychiatric disturbances by inducing in the patient a major motor seizure by applying a brief intense electrical current to the patient's head.

(b) *Classification.* (1) Class II (special controls) when the device is intended to treat catatonia or a severe major depressive episode (MDE) associated with major depressive disorder (MDD) or bipolar disorder (BPD) in patients age 13 years and older who are treatment-resistant or who require a rapid response due to the severity of their psychiatric or medical condition. The special controls for this device are:

(i) The technical parameters of the device, including waveform, output mode, pulse duration, frequency, train delivery, maximum charge and energy, and the type of impedance monitoring system must be fully characterized to ensure that the device performance characteristics are consistent with existing clinical performance data.

(ii) Non-clinical testing data must confirm the electrical characteristics of the output waveform.

(iii) Components of the device that come into human contact must be demonstrated to be biocompatible.

(iv) Performance data must demonstrate electrical and mechanical safety and the functioning of all safety features built into the device including the static and dynamic impedance monitoring system.

(v) Appropriate analysis/testing must validate electromagnetic compatibility.

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

(vii) Performance data must demonstrate electrical performance, adhesive integrity, and physical and chemical stability of the stimulation electrodes.

(viii) The labeling for the device must include the following:

(A) Information related to generic adverse events associated with electroconvulsive therapy device (ECT) treatment;

(B) Instructions must contain the following specific recommendations to the user of the device:

(*1*) Conduct of pre-ECT medical and psychiatric assessment (including pertinent medical and psychiatric history, physical examination, anesthesia assessment, dental assessment, and other studies as clinically appropriate);

(*2*) Use of patient monitoring during the procedure;

(*3*) Use of general anesthesia and neuromuscular blocking agents;

(*4*) Use of mouth/dental protection during the procedure;

(*5*) Use of EEG monitoring until seizure termination;

(*6*) Instructions on electrode placement, including adequate skin preparation and use of conductive gel; and

(*7*) Cognitive status monitoring prior to beginning ECT and during the course of treatment via formal neuropsychological assessment for evaluating specific cognitive functions (*e.g.*, orientation, attention, memory, executive function).

(C) Clinical training needed by users of the device;

(D) Information on the patient population in which the device is intended to be used;

(E) Information on how the device operates and the typical course of treatment;

(F) A detailed summary of the clinical testing, which includes the clinical outcomes associated with the use of the device, and a summary of adverse events and complications that occurred with the device;

(G) A detailed summary of the device technical parameters;

(H) Where appropriate, validated methods and instructions for reprocessing of any reusable components;

(I) The following statement, prominently placed: ''Warning: ECT device use may be associated with: disorientation, confusion, and memory problems''; and

(J) Absent performance data demonstrating a beneficial effect of longer term use, generally considered treatment in excess of 3 months, the following statement, prominently placed: ''Warning: When used as intended this device provides short-term relief of symptoms. The long-term safety and effectiveness of ECT treatment has not been demonstrated.''

(ix) Patient labeling must be provided and include:

(A) Relevant contraindications, warnings, precautions;

(B) A summation of the clinical testing, which includes the clinical outcomes associated with the use of the device, and a summary of adverse events and complications that occurred with the device;

(C) Information on how the device operates and the typical course of treatment;

(D) The potential benefits;

(E) Alternative treatments;

(F) The following statement, prominently placed: ''Warning: ECT device use may be associated with: Disorientation, confusion, and memory problems'';

(G) Absent performance data demonstrating a beneficial effect of longer term use, generally considered treatment in excess of 3 months, the following statement, prominently placed: ''Warning: When used as intended this device provides short-term relief of symptoms. The long-term safety and effectiveness of ECT treatment has not been demonstrated''; and

(H) The following statements on known risks of ECT, absent performance data demonstrating that these risks do not apply:

(*1*) ECT treatment may be associated with disorientation, confusion and memory loss, including short-term (anterograde) and long-term (autobiographical) memory loss following treatment. Based on the majority of clinical evidence, these side effects tend to go away within a few days to a few months after the last treatment with ECT. Although the incidence of permanent cognitive memory loss was not supported by the clinical literature, some patients have reported a permanent loss of memories of personal life events (*i.e.*, autobiographical memory);

(*2*) Patients treated with ECT may experience manic symptoms (including euphoria and/or irritability, impulsivity, racing thoughts, distractibility, grandiosity, increased activity, talkativeness, and decreased need for sleep) or a worsening of the psychiatric symptoms they are being treated for; and

(*3*) The physical risks of ECT may include the following (in order of frequency of occurrence):

(*i*) Pain/somatic discomfort (including headache, muscle soreness, and nausea);

(*ii*) Skin burns;

(*iii*) Physical trauma (including fractures, contusions, injury from falls, dental and oral injury);

(*iv*) Prolonged or delayed onset seizures;

(*v*) Pulmonary complications (hypoxemia, hypoventilation, aspiration, upper-airway obstruction);

(*vi*) Cardiovascular complications (cardiac arrhythmias, heart attack, high or low blood pressure, and stroke); and

(*vii*) Death.

(2) *Classification:* Class III (premarket approval) for the following intended uses: schizophrenia, bipolar manic states, schizoaffective disorder, schizophreniform disorder, and catatonia or a severe MDE associated with MDD or BPD in:

(i) Patients under 13 years or

(ii) Patients 13 years and older who are not treatment-resistant or who do not require a rapid response due to the severity of their psychiatric or medical condition.

(c) *Date premarket approval application (PMA) or notice of completion of product development protocol (PDP) is required.* A PMA or notice of completion of a PDP is required to be filed with FDA on or before March 26, 2019, for any electroconvulsive therapy device with an intended use described in paragraph (b)(2) of this section, that was in commercial distribution before May 28, 1976, or that has, on or before March 26, 2019, been found to be substantially equivalent to any electroconvulsive therapy device with an intended use described in paragraph (b)(2) of this section, that was in commercial distribution before May 28, 1976. Any other electroconvulsive therapy device with an intended use described in paragraph (b)(2) of this section shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

[83 FR 66123, Dec. 26, 2018]

§ 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 ateriovenous malformations. This does not include cyanoacrylates and other embolic 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]

§ 882.5955 Temporary coil embolization assist device.

(a) *Identification.* A temporary coil embolization assist device is a prescription device intended for temporary use in the neurovasculature to mechanically assist in the embolization of intracranial aneurysms with embolic coils. The device is delivered into the neurovasculature with an endovascular approach. This device is not intended to be permanently implanted and is removed from the body when the procedure is completed.

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

(1) Clinical performance testing of the device must demonstrate the device performs as intended for temporary use as an endovascular device to assist in the coil embolization of intracranial aneurysms and must evaluate all adverse events, including tissue or vessel damage that could lead to dissection, perforation, hemorrhage, or vasospasm, thrombo-embolic events, and coil entanglement.

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

(3) Non-clinical performance testing must demonstrate the device performs as intended under anticipated conditions of use, including:

(i) Mechanical testing to demonstrate the device can withstand anticipated tensile, torsional, compressive, and tip deflection forces;

(ii) Mechanical testing to evaluate the radial forces exerted by the device;

(iii) Simulated use testing to demonstrate the device can be delivered to the target location in the neurovasculature and is compatible with embolic coils;

(iv) Dimensional verification testing;

(v) Radiopacity testing; and

(vi) Performance testing to evaluate the coating integrity and particulates under simulated use conditions.

(4) Animal testing under anticipated use conditions must evaluate all adverse events, including damage to vessels or tissues.

(5) Performance data must support the sterility and pyrogenicity of the device.

(6) Performance data must support the shelf life of the device by demonstrating continued sterility, package integrity, and device functionality over the labeled shelf life.

(7) The labeling must include:

(i) Instructions for use;

(ii) A detailed summary of the device technical parameters, including compatible delivery catheter dimensions and device sizing information;

(iii) A summary of the clinical testing results, including a detailed summary of the device- and procedure-related complications and adverse events; and

(iv) A shelf life.

[86 FR 70733, Dec. 13, 2021]

§ 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]

PART 884—OBSTETRICAL AND GYNECOLOGICAL DEVICES

Subpart A—General Provisions

Subpart B—Obstetrical and Gynecological Diagnostic Devices

Subpart C—Obstetrical and Gynecological Monitoring Devices