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: