August 16, 2018

Brainsway Ltd.
℅ Ahava Stein
A.Stein - Regulatory Affairs Consulting
20 Hata'as St.
Kfar Saba, 4442520 Israel

Re: DEN170078
Trade/Device Name: Brainsway Deep Transcranial Magnetic Stimulation System
Regulation Number: 21 CFR 882.5802
Regulation Name: Transcranial magnetic stimulation system for neurological and psychiatric disorders and conditions
Regulatory Class: Class II
Product Code: QCI
Dated: September 26, 2017
Received: September 29, 2017

Dear Ahava Stein:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the Brainsway Deep Transcranial Magnetic Stimulation (DTMS) System, a prescription device under 21 CFR Part 801.109 with the following indications for use:

> The Brainsway Deep Transcranial Magnetic Stimulation System is intended to be used as an adjunct for the treatment of adult patients suffering from Obsessive-Compulsive Disorder.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the Brainsway DTMS System, and substantially equivalent devices of this generic type, into Class II under the generic name transcranial magnetic stimulation system for neurological and psychiatric disorders and conditions.

FDA identifies this generic type of device as:

> **Transcranial magnetic stimulation system for neurological and psychiatric disorders and conditions.** 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.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On September 29, 2017, FDA received your De Novo requesting classification of the Brainsway DTMS System. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Brainsway DTMS System into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request, FDA has determined that, for the previously stated indications for use, the Brainsway DTMS System can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Table 1 – Identified Risks to Health and Mitigation Measures

Identified Risk	**Mitigation Measures**
Seizure	Non-clinical performance testing Labeling
Thermal injury	Non-clinical performance testing Thermal safety testing Electrical safety testing Software verification, validation, and hazard analysis Labeling
Hearing loss	Non-clinical performance testing Labeling
Scalp discomfort, dizziness, nausea, pain in neck or jaw, headache, or other adverse effects due to treatment	Labeling
Adverse tissue reaction	Biocompatibility evaluation Labeling
Electrical shock	Electrical safety testing Labeling
Device failure due to interference with other devices	Electromagnetic compatibility testing Electrical safety testing Labeling

In combination with the general controls of the FD&C Act, the transcranial magnetic stimulation system for neurological and psychiatric disorders and conditions is subject to the following special controls:

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:
    a. Magnetic pulse output testing;
    b. Magnetic and electrical field testing;
    c. Testing of the safety features built into the device; and
    d. Testing of the sound levels patients are exposed to during device use.

5. The physician and patient labeling must include the following:
    a. The risks and benefits associated with use of the device.
    b. 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.
    c. 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.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the transcranial magnetic stimulation system for neurological and psychiatric disorders and conditions they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and if applicable, the electronic product radiation control provisions (Sections 531-542 of the FD&C Act); 21 CFR 1000-1050.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

If you have any questions concerning the contents of the letter, please contact John R. Doucet, PhD at 301-796-6474.

Sincerely,

Angela C. Krueger -S

Angela C. Krueger
Deputy Director, Engineering and Science Review
Office of Device Evaluation
Center for Devices and Radiological Health