March 8, 2019

Brainsway Ltd.
% Janice Hogan
Partner
Hogan Lovells US LLP
1735 Market St., 23rd Floor
Philadelphia, Pennsylvania 19103

Re: K183303
Trade/Device Name: Brainsway Deep TMS 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: February 5, 2019
Received: February 5, 2019

Dear Janice Hogan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the 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 Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, 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).

Sincerely,

Pamela D. Scott -S

Digitally signed by Pamela D. Scott -S
Date: 2019.03.08 22:30:01 -05'00'

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183303

Device Name
Brainsway Deep TMS System

Indications for Use *(Describe)*
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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY
K183303

Brainsway Deep TMS System

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

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February 7, 2019

Device Name

Brainsway Deep TMS System

Classification Names

Transcranial magnetic stimulation system for neurological and psychiatric disorders and conditions

Classification

21 CFR 882.5802, Class II, Product Code QCI

Predicate Devices

Brainsway Deep TMS System (DEN170078) (predicate)
Brainsway Deep TMS System (K173540) (reference device)

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.

Device Description

The proposed device is a modification to the Brainsway Deep TMS System that was cleared under DEN170078. Brainsway has implemented minor changes to the helmet configuration, improved the user interface, modified the measurement method, and made other minor component changes. None of these changes alter the technical specifications for the device, which maintains the same voltage and current, same frequencies, and same electrical mains compatibility. The same technological features have previously been cleared by FDA for use in major depressive disorder in K173540.

Consistent with the predicate and reference device, the proposed Brainsway Deep TMS System enables direct non-invasive activation of deep brain structures. Transcranial magnetic stimulation (TMS) is a non-invasive technique used to apply brief magnetic pulses to the brain. The pulses are administered by passing high currents through an electromagnetic coil placed adjacent to a patient's scalp. The pulses induce an electric field in the underlying brain tissue. When the induced field is above a certain threshold, and is directed in an appropriate orientation relative the brain's neuronal pathways, localized axonal depolarizations are produced, thus activating neurons in the targeted brain structure.

Comparison of Technological Characteristics

Parameter	Subject Device (K183303)	Predicate Device (DEN170078)	Reference Device (K173540)	Comparison
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.	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.	The Brainsway Deep TMS is indicated for the treatment of depressive episodes in adult patients suffering from Major Depressive Disorder who failed to achieve satisfactory improvement from previous anti-depressant medication treatment in the current episode.	**SAME as Predicate**
Classification/ Product Code	21 CFR 882.5802/QCI	21 CFR 882.5802/QCI	21 CFR 882.5805/OBP	**SAME as Predicate**

Parameter	Subject Device (K183303)	Predicate Device (DEN170078)	Reference Device (K173540)	Comparison
Treatment Parameters	OCD Treatment Parameters: • Magnetic Field Intensity: 100% of the patient's observed motor threshold • Frequency: 20 Hz • Train Duration: 2 seconds • Inter-train interval: 20 seconds • Number of trains: 50 • Magnetic Pulses per Session: 2000 • Treatment Session Duration: Approximately 18.3 minutes • Sessions per week: 5 • 5 daily sessions for 5 weeks, 4 daily sessions for 1 week	OCD Treatment Parameters: • Magnetic Field Intensity: 100% of the patient's observed motor threshold • Frequency: 20 Hz • Train Duration: 2 seconds • Inter-train interval: 20 seconds • Number of trains: 50 • Magnetic Pulses per Session: 2000 • Treatment Session Duration: Approximately 18.3 minutes • Sessions per week: 5 • 5 daily sessions for 5 weeks, 4 daily sessions for 1 week	MDD Treatment Parameters: • Magnetic Field Intensity: 120% of the patient's observed motor threshold. • Frequency: 18 Hz • Train Duration: 2 seconds • Inter-train interval: 20 sec • Number of trains: 55 • Magnetic Pulses per Session: 1980 • Treatment Session Duration: Approximately 20.2 minutes • Sessions per week: 5 • 5 daily sessions for 4 weeks • Bi-weekly sessions for another 12 weeks (optional maintenance treatments)	**SAME as Predicate**
Area of brain to be stimulated	Prefrontal Cortex	Prefrontal Cortex	Prefrontal Cortex	**SAME as and Predicate and Reference Device**
Configuration	Biphasic	Biphasic	Biphasic	**SAME as Predicate and Reference Device**
Core material	Air	Air	Air	**SAME as Predicate and Reference**

Parameter	Subject Device (K183303)	Predicate Device (DEN170078)	Reference Device (K173540)	Comparison
Peak Electric Current	6000 A	5000-6000 A	6000 A	**Similar to Predicate and SAME as Reference Device**
Maximal Operating Voltage	1.7 kV	1.7 kV	1.7 kV	**SAME as Predicate and Reference Device**
Amplitude in Standard Motor Threshold (SMT) units	0.6-1.4	0.6-1.4	0.6-1.4	**SAME as Predicate and Reference Device**
Pulse width (usec)	324	324	369	**SAME as Predicate**
Frequency range (Hz)	0.1-50	1-50	0.1-50	**SAME as Reference Device**
Pulse train duration range (sec)	1-20	1-20	1-20	**SAME as Predicate and Reference Device**
Inter-train interval range (sec)	10-60	10-60	10-60	**SAME as and Reference Device**
Maximum trains per session	~140	~140	~140	**SAME as Predicate and Reference Device**
Maximum # of pulses per session (cumulative exposure)	5000	5000	~5000	**SAME as Predicate and Reference Device**

Parameter	Subject Device (K183303)	Predicate Device (DEN170078)	Reference Device (K173540)	Comparison
Physical unit of amplitude setting (e.g., coil current, peak magnetic field) at coil & its relation to SMT unit: Electric field at 1.5cm from coil (equivalent to 1.0 SMT [V/m])	100	100	100	**SAME as Predicate and Reference Device**
Cart Dimensions	680 mm (L) x 688mm (W)	680 mm (L) x 625mm (W)	680 mm (L) x 688mm (W)	**Device**
Maximum System Height	2050 mm	2050 mm	2050 mm	**SAME as Predicate and Reference Device**
Voltage	100-240 VAC	110-120 VAC	100-240 VAC	**SAME as Reference Device**
Frequency	50/60 Hz	50/60 Hz	50/60 Hz	**SAME as Predicate and Reference Device**
Coil's Operating Temperature:	10°C to 30°C	15 ºC to 30 ºC	10°C to 31°C	**SAME as Reference Device**
Storage Temperature	-20 ºC to 60 ºC	-20 ºC to 60 ºC	-20 ºC to 60 ºC	**SAME as Predicate and Reference Device**
Atmospheric Pressure Range	500 hPa to 1060 hPa	500 hPa to 1060 hPa	500 hPa to 1060 hPa	**SAME as Predicate and Reference Device**

Parameter	Subject Device (K183303)	Predicate Device (DEN170078)	Reference Device (K173540)	Comparison
Relative Humidity Range	10% to 80% Non-Condensing	10% to 80% Non-Condensing	10% to 80% Non-Condensing	**SAME as Predicate and Reference**

Both the subject and predicate device have an almost identical movable cart that is used to place the TMS neurostimulator and the cooling system. In both the subject and predicate device, the positioning device is connected to the cart. Although the subject device has a slightly larger cart as compared to the predicate device, this difference does not raise new questions of safety and effectiveness.

Further, both the subject and predicate device consist of a TMS neurostimulator that delivers electrical stimulation to the brain, enabling a controlled output, frequency, pulse duration and indication of coil temperature. Although the predicate device uses commercially available TMS neurostimulators and the subject device uses the Brainsway Stimulator, this difference does not raise new of different questions of safety and effectiveness as demonstrated through performance testing. Further, the identical Brainsway Stimulator was cleared in the reference device, further establishing substantial equivalence.

The subject device has a substantially similar cooling system as compared to the predicate device. The Cooling System continues to consist of an external unit and an air hose streaming the cooled air into the helmet. The air flow cools the coils during pulse trains and maintains them at ambient temperature (less than 30^{o}C). The only difference between the cooling system cleared in the predicate device as compared to the subject device is that the proposed cooling system has a better and stronger compressor, which leads to improved performance as demonstrated in the repeated cooling system development tests. This identical cooling system has been cleared in the reference device further demonstrating substantial equivalence.

Further, the positioning device of the subject and the predicate device continues to feature an adjustable arm that enables the rotation of the helmet around three orthogonal rotation axes (XYZ axes). The positioning device continues to enable accurate and comfortable displacement and positioning of the coil over the patient's head.

The helmet used in both the subject and predicate device are nearly identical. The frontal contour of the helmet has changed slightly from straight to concave configuration. In addition, a transparent plastic guide through which a grid can be observed has been added. The guide shows a red vertical line and a black horizontal line with end markings for positioning. This difference does not raise new or different questions of safety and effectiveness.

The H-Coil of both the subject and predicate device are nearly identical. Although the diameter and cross section of the copper wire of the H-Coil is slightly larger in the subject device as compared to the predicate device, this difference does not raise new of different questions of safety and effectiveness, as demonstrated through performance testing.

Although the predicate used two flexible rulers (medial & lateral) that were attached along the midline of the Cap to assist in proper helmet positioning whereas the subject device uses a grid, this difference introduces no new questions of safety and effectiveness as demonstrated through completed performance testing.

Performance Data

The following tests were performed to validate the modifications to the device:

- Software verification and validation;
- Electrical safety in accordance with IEC 60601-1 and EMC in accordance with IEC 60601-1-2;
- Bench performance testing.

In all instances, the subject device functions as intended and meets all the same acceptance criteria as the predicate and reference device.

Substantial Equivalence

The modified Brainsway Deep TMS System has the same intended use and indications, principles of operation, and similar technological characteristics as the previously cleared predicate device. The minor differences in the technical characteristics of the updated device do not raise any new or different questions of safety or effectiveness. Performance data demonstrates that the modified device is safe and effective for its intended use. Thus, the modified Brainsway Deep TMS System is substantially equivalent.