May 3, 2018

Brainsway Ltd.
% Ahava Stein
A. Stein-Regulatory Affairs Consulting Ltd.
20 Hata'as Str., Suite 102
Kfar Saba 4442520 Israel

Re: K173540
Trade/Device Name: Brainsway Deep TMS System
Regulation Number: 21 CFR 882.5805
Regulation Name: Repetitive Transcranial Magnetic Stimulation System
Regulatory Class: Class II
Product Code: OBP
Dated: March 29, 2018
Received: April 2, 2018

Dear Ahava Stein:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

William J. Heetderks -S
2018.05.03 20:54:06 -04'00'

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)*
TBD

Device Name
Brainsway Deep TMS System

Indications for Use *(Describe)*
The Brainsway Deep TMS System 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.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) SUMMARY

BRAINSWAY DEEP TMS SYSTEM

510(k) Number K173540

Applicant Name:

Company Name: Brainsway Ltd
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Tel: +972-2-5813140
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Fax: +972-9-7668534
E-mail: ahava@asteinrac.com

Date Prepared: November 11, 2017

Trade Name: Brainsway Deep TMS System

Classification Name: CFR Classification section 882.5805; (Product Code OBP)

Classification: Class II Medical Device

Predicate Device:

Brainsway Deep TMS System is substantially equivalent to the previously cleared, Brainsway Deep TMS System, also manufactured by Brainsway Ltd.

Device	Manufacturer	510(k) No.
Brainsway Deep TMS System	Brainsway Ltd.	K122288

Device Description:

The 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.

The FDA cleared Brainsway Deep TMS System is composed of the following main components:

1. An Electromagnetic Coil
2. A TMS Neurostimulator
3. A Cooling System
4. A Positioning Device
5. A Cart

Intended Use/Indication for Use:

The Brainsway Deep TMS System 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..

Performance Standards:

Brainsway Deep TMS System complies with the following FDA recognized consensus standards:

- EC 60601-1 Medical Electrical Equipment - Part 1: General requirements for safety 1: collateral standard: safety requirements for medical electrical systems (2005 +A12012)
- IEC 60601-1-2 Medical Electrical Equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and test (Ed 3 2007)
- IEC 62304 Medical Devices Software Software life-cycle processes (2006 + A1:2015)

Non-Clinical (Bench) Performance Data:

Tests were conducted on the modified Brainsway Deep TMS System. The tests were performed in a similar manner as to the tests performed with the cleared predicate device and according to the FDA Guidance Document *Class II Special Controls Guidance Document: Repetitive Transcranial Magnetic Stimulation (rTMS) Systems*. These tests included Output Waveform, Electrical Field Spatial Distribution and Magnetic Field Strength Gradient Testing. Additional performance testing included software validation testing in compliance with FDA guidelines for software validation and IEC 62304 standard requirements. The results of the performance tests demonstrated that the Brainsway Deep TMS System is substantially equivalent to the predicate device.

Animal Performance Data / Histology Data:

Not Applicable

Clinical Performance Data:

Not Applicable

Substantial Equivalence:

The modified device has the same intended use and indications for use as the cleared Brainsway Deep TMS System. Both the modified device and the cleared Brainsway Deep TMS System are similar in terms of their intended prescription use only, suitable for adult population, indicated for anatomical sites according to indications for use and to be used in hospital or clinic settings.

The basic components of modified Brainsway DTMS System are still similar to the cleared, predicate device and have the same mechanism of operation and use the same underlying technology. The performance characteristics, including the Output Waveform, Electrical Field Spatial Distribution and Magnetic Field Strength Gradient are substantially equivalent to the previously cleared Brainsway DTMS System, as demonstrated in the performance testing.

Using the modified or the cleared Brainsway devices, the user can determine the treatment settings, record patient data, etc. The modified device, as the cleared device, introduces similar safety features and complies with same relevant consensus standards, including software validation. That is, the new stimulator software has been validated to ensure its proper performance.

All device modifications were tested under the design control activities, including in-house bench testing of the coil and cooling system, software validation in compliance with international standards and FDA guidelines, as well as testing for compliance with relevant consensus standards for electrical and mechanical safety, electromagnetic compatibility and software validation. All potential hazards were mitigated in the performance testing conducted as part of the design control activities. All performance activities show that the modifications made to the cleared device do not pose any new safety and effectiveness concerns. Furthermore, the labeling material was revised to support the above-mentioned modifications.

A comparison of the modified device and the predicate device is presented in the following table:

Technological Characteristic	**Modified Brainsway Deep TMS System (K173540)**	**Brainsway Deep TMS System (K122288)**
Product Code, Class	OBP Class II	OBP Class II
Indications for Use	The Brainsway Deep TMS System 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.	The Brainsway Deep TMS System 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.
Target Population	Adult subjects with Major Depressive Disorder	Adult subjects with Major Depressive Disorder
Anatomical Sites	Head – stimulation to the prefrontal cortex	Head – stimulation to the prefrontal cortex
Environment Used	Hospitals, Clinics	Hospitals, Clinics
Energy Used / Delivered	Electromagnetic Energy is delivered	Electromagnetic Energy is delivered
Design:	The Brainsway DTMS System design is based on applying transcranial magnetic stimulation by means of repetitive pulse trains at a predetermined frequency.	The Brainsway DTMS System design is based on applying transcranial magnetic stimulation by means of repetitive pulse trains at a predetermined frequency.
- Mechanism of Action	The Brainsway DTMS System is an electromechanical instrument that produces and delivers brief duration, rapidly alternating (pulsed) magnetic fields to induce electrical currents in localized regions of the prefrontal cortex. This is a non-invasive tool for the stimulation of cortical neurons for the treatment of adult patients with Major Depressive Disorder (MDD).	The Brainsway DTMS System is an electromechanical instrument that produces and delivers brief duration, rapidly alternating (pulsed) magnetic fields to induce electrical currents in localized regions of the prefrontal cortex. This is a non-invasive tool for the stimulation of cortical neurons for the treatment of adult patients with Major Depressive Disorder (MDD).

Technological Characteristic	Modified Brainsway Deep TMS System (K173540)	Brainsway Deep TMS System (K122288)
- Components	The Brainsway DTMS System consists of the following components: - Mobile Cart - Coil & Helmet Unit - Positioning Arm - Cooling System - TMS stimulator & Software (Brainsway)	The Brainsway DTMS System consists of the following components: - Mobile Cart - Coil & Helmet Unit - Positioning Arm - Cooling System - TMS stimulator & Software (Magstim)
- Accessories	The Brainsway DTMS System consists of the following accessories: - Head Cap - Head Positioning Straps - Earplugs	The Brainsway DTMS System consists of the following accessories: - Head Cap - Head Positioning Straps - Earplugs
- Features	The Brainsway DTMS System consists of the following features: - Determination of Motor Threshold (MT) - Coil Positioning - Administration of Treatment - System Management, including patient record keeping	The Brainsway DTMS System consists of the following features: - Determination of Motor Threshold (MT) - Coil Positioning - Administration of Treatment
- Dimensions	Cart Dimensions: 680mm (L) x 688mm (W) (26.7”(L) x 27”(W))	Cart Dimensions: 680mm (L) x 625mm (W) (27”(L) x 25”(W))
- Weight	142 kg (313lbs)	122.5 kg (270lbs)
Performance	MDD Treatment Parameters: Magnetic Field Intensity: 120% of the patient’s observed motor threshold. - Frequency: 18 Hz. - Train duration: 2 sec. - 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)	MDD Treatment Parameters: Magnetic Field Intensity: 120% of the patient’s observed motor threshold. - Frequency: 18 Hz. - Train duration: 2 sec. - 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)
Human Factors	The Brainsway DTMS System uses its own TMS stimulator software for parameter configuration. Patient positioning and MT determination are done manually.	The Brainsway DTMS System uses the Magstim TMS stimulator software for parameter configuration. Patient positioning and MT determination are done manually.
Standards Met	IEC 60601-1 IEC 60601-1-2 IEC 62304	IEC 60601-1 IEC 60601-1-2 IEC 62304
Materials	Head Cap - biocompatible material	Head Cap - biocompatible material
Biocompatibility	Materials are biocompatible	Materials are biocompatible

Technological Characteristic	Modified Brainsway Deep TMS System (K173540)	Brainsway Deep TMS System (K122288)
Compatibility With the Environment and Other Devices	The Brainsway DTMS System is compliant with the IEC 60601-1-2 (EMC Safety) standard.	The Brainsway DTMS System is compliant with the IEC 60601-1-2 (EMC Safety) standard.
Sterility	Not Applicable	Not Applicable
Electrical Safety	Power Requirements: 110-120 VAC / 60 Hz 220-240 VAC / 50 Hz The Brainsway DTMS System is compliant with the IEC 60601-1 standard.	Power Requirements: 110-120 VAC / 60 Hz 220-240 VAC / 50 Hz The Brainsway DTMS System is compliant with the IEC 60601-1 standard.
Mechanical Safety	The Brainsway DTMS System is compliant with the IEC 60601-1 standard.	The Brainsway DTMS System is compliant with the IEC 60601-1 standard.
Chemical Safety	Not Applicable	Not Applicable
Thermal Safety	The Brainsway DTMS System is compliant with the IEC 60601-1 standard.	The Brainsway DTMS System is compliant with the IEC 60601-1 standard.
Radiation Safety	The Brainsway DTMS System is compliant with the IEC 60601-1-2 (EMC Safety) standard.	The Brainsway DTMS System is compliant with the IEC 60601-1-2 (EMC Safety) standard.

Conclusions:

Consequently, it can be concluded that the modified Brainsway Deep TMS System is substantially equivalent to the predicate Brainsway Deep TMS System, cleared under 510(k) K122288 and therefore, the modified Brainsway Deep TMS System can be legally marketed in the USA.