June 2, 2021

Brainsway Ltd.
% Ahava Stein
Regulatory Consultant
A. Stein Regulatory Affairs Consulting Ltd.
18 Hataas St., Suite 102
Kfar Saba, 4442520
Israel

Re: K203616
Trade/Device Name: Brainsway Deep (DTMS) 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: QMD

Dear Ahava Stein:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated April 16, 2021. Specifically, FDA is updating this SE Letter because FDA has created a new product code to better categorize your device technology.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Pamela Scott, OHT5: Office of Neurological and Physical Medicine Devices, 301-796-5433, PamelaD.Scott@fda.hhs.gov.

Sincerely,

Pamela D. Scott -S

Digitally signed by Pamela D. Scott -S
Date: 2021.06.02 12:07:38 -04'00'

Pamela Scott
Assistant Director
DHT5B: Division of Neuromodulation and Physical Medicine Devices
OHT5: Office of Neurological and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

April 16, 2021

Brainsway Ltd.
% Ahava Stein
Regulatory Consultant
A. Stein Regulatory Affairs Consulting Ltd.
18 Hataas St., Suite 102
Kfar Saba, 4442520
Israel

Re: K203616
Trade/Device Name: Brainsway Deep (DTMS) 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: March 24, 2021
Received: March 29, 2021

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. 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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-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: 2021.04.16 19:44:43 -04'00'

Pamela Scott
Assistant Director
DHT5B: Division of Neuromodulation
and Physical Medicine Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203616

Device Name
Brainsway Deep TMS System

Indications for Use *(Describe)*
The Brainsway Deep Transcranial Magnetic Stimulation System is indicated to be used as an aid in short-term smoking cessation for adults.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) SUMMARY

BRAINSWAY DEEP TMS SYSTEM

510(k) Number K203616

Applicant Name:
Company Name: Brainsway Ltd
Address: Brainsway Ltd.
19 Hartom St. (Bynet Bldg)
Har Hotzvim, Jerusalem, ISRAEL 9777518
Tel: +972-2-5813140
Fax: +972-2-5812517
E-mail: ahava@asteinrac.com

Contact Person:
Official Correspondent: Ahava Stein
Company Name: A. Stein – Regulatory Affairs Consulting Ltd.
Address: 18 Hata'as Str., Suite 102
Kfar Saba 4442520 Israel
Tel: + 972-9-7670002
Fax: +972-9-7668534
E-mail: ahava@asteinrac.com

Date Prepared: February 21, 2021

Trade Name: Brainsway Deep TMS System

Classification Name: CFR Classification section 882.5802; (Product Code QMD)

Classification: Class II Medical Device

Predicate Device:

The subject device is a modification of the Brainsway Deep TMS System ("predicate device") that was cleared in 510(k) document no. K200957. Similar modifications have been made to the Brainsway Deep TMS System cleared in K183303 ("reference device").

Predicate	Device	Manufacturer	510(k) No.
Main	Brainsway Deep TMS System	Brainsway Ltd.	K200957
Reference	Brainsway Deep TMS System	Brainsway Ltd.	K183303

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

1. Cart
   a) TMS Neurostimulator
   b) Cooling System
   c) Positioning Device
2. Helmet
   a) Aiming Apparatus (i.e., ruler/grid)
   b) Electromagnetic Coil (H4-Coil)
   c) Cap

Intended Use/Indication for Use:

The Brainsway Deep Transcranial Magnetic Stimulation System is indicated to be used as an aid in short-term smoking cessation for adults.

Performance Standards:

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

- IEC 60601-1 Medical Electrical Equipment - Part 1: General requirements for basic safety and essential performance (Ed 3.1, 2005 + CORR.1:2006 + CORR.2:2007 + A1:2012 AND 2006 + AC:2010 + A1:2013)
- 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 4 2014)
- IEC 62304 Medical Devices Software life-cycle processes (2006 + A1:2015)
- ISO 10993-5 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10 Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity
- ISO 14971 Medical devices - Application of risk management to medical devices

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 devices 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 electrical and mechanical safety testing, electromagnetic compatibility testing and 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 subject device is substantially equivalent to the Brainsway Deep TMS System intended for use as an aid for short-term Smoking Cessation, also manufactured by Brainsway Ltd., and cleared in 510(k) No. K200957 (main predicate device). The subject device is also substantially equivalent to the Brainsway Deep TMS System for the treatment of OCD, cleared in 510(k) K183303 (reference predicate device), regarding the device modifications, including the new Brainsway stimulator component and minor modifications to the device cart, cooling system, coil wire and helmet.

A comparison table is provided below comparing the intended use and basic technological characteristics of the subject Brainsway Deep TMS System to the intended use and basic technological characteristics of the previously cleared Brainsway Deep TMS Systems.

A Discussion of the Similarities and Differences between the modified Brainsway Deep TMS System and the previously cleared Brainsway Deep TMS Systems is found following the comparison table.

Technological Characteristic	Modified Brainsway Deep TMS System	Brainsway Deep TMS System Main Predicate (K200957)	Brainsway Deep TMS System Reference Predicate (K183303)
Classification/ Product Code	21 CFR 882.5802	21 CFR 882.5802	21 CFR 882.5802
Product Code, Class	QMD Class II	QCI Class II	QCI Class II
Indications for Use	The Brainsway Deep Transcranial Magnetic Stimulation System is indicated to be used as an aid in short-term smoking cessation for adults.	The Brainsway Deep Transcranial Magnetic Stimulation System is indicated to be used as an aid in short-term smoking cessation for adults.	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.
Target Population	Adult subjects with smoking addiction	Adult subjects with smoking addiction	Adult subjects with Obsessive Compulsive Disorder
Anatomical Sites	Head – stimulation to the prefrontal cortex and insula	Head – stimulation to the prefrontal cortex and insula	Head – stimulation to the prefrontal cortex
Environment Used	Hospitals, Clinics	Hospitals, Clinics	Hospitals, Clinics
Energy Used / Delivered	Electromagnetic Energy is 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.	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 and insula. This is a non-invasive tool for the stimulation of cortical neurons as an aid in short-term smoking cessation.	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 and insula. This is a non-invasive tool for the stimulation of cortical neurons as an aid in short-term smoking cessation.	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 Obsessive Compulsive Disorder.

Technological Characteristic	Modified Brainsway Deep TMS System	Brainsway Deep TMS System Main Predicate (K200957)	Brainsway Deep TMS System Reference Predicate (K183303)
- System Components	The Brainsway DTMS System consists of the following components: - Mobile Cart - Cooling System - Positioning Arm - Brainsway TMS stimulator & SW - Helmet & Aiming Apparatus - H4/HADD-Coil	The Brainsway DTMS System consists of the following components: - Mobile Cart - Cooling System - Positioning Arm - Magstim TMS stimulator - Helmet - H4/HADD-Coil	The Brainsway DTMS System consists of the following components: - Mobile Cart - Cooling System - Positioning Arm - Brainsway TMS stimulator & SW - Helmet & Aiming Apparatus - H7/HAC-Coil
- System 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	The Brainsway DTMS System consists of the following accessories: - Head Cap - Head Positioning Straps - Earplugs
- Features / Operational Procedures	The Brainsway DTMS System consists of the following features: - Determination of Motor Threshold - Coil Positioning - Administration of Treatment - System Management, including patient record keeping	The Brainsway DTMS System consists of the following features: - Determination of Motor Threshold - Coil Positioning - Administration of Treatment	The Brainsway DTMS System consists of the following features: - Determination of Motor Threshold - Coil Positioning - Administration of Treatment - System Management, including patient record keeping
- 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))	Cart Dimensions: 680mm (L) x 688mm (W) (26.7”(L) x 27”(W))
- Weight	142 kg (313lbs)	122.5 kg (270lbs)	142 kg (313lbs)
Performance	Treatment Parameters: - Magnetic Field Intensity: 120% of the patient’s observed motor threshold. - Frequency: 10 Hz. - Train duration: 3 sec. - Inter-train interval: 15 sec. - Number of trains: 60 - Magnetic Pulses per Session: 1800 - Tx Session Duration: ~20 min - 5 daily sessions for 3 weeks, followed by one weekly session for another 3 weeks	Treatment Parameters: - Magnetic Field Intensity: 120% of the patient’s observed motor threshold. - Frequency: 10 Hz. - Train duration: 3 sec. - Inter-train interval: 15 sec. - Number of trains: 60 - Magnetic Pulses per Session: 1800 - Tx Session Duration: ~20 min - 5 daily sessions for 3 weeks, followed by one weekly session for another 3 weeks	Treatment Parameters: - Magnetic Field Intensity: 100% of the patient’s observed motor threshold. - Frequency: 20 Hz. - Train duration: 2 sec. - Inter-train interval: 20 sec. - Number of trains: 50 - Magnetic Pulses per Session: 2000 - Tx Session Duration: ~18 min - 5 daily sessions for 5 weeks and 4 daily sessions during the sixth week

Technological Characteristic	Modified Brainsway Deep TMS System	Brainsway Deep TMS System Main Predicate (K200957)	Brainsway Deep TMS System Reference Predicate (K183303)
Coil's Operating Temperature:	10°C to 30°C	15 ºC to 30 ºC	10°C to 30°C
Storage Temperature	-20 ºC to 60 ºC	-20 ºC to 60 ºC	-20 ºC to 60 ºC
Atmospheric Pressure Range	500 hPa to 1060 hPa	500 hPa to 1060 hPa	500 hPa to 1060 hPa
Relative Humidity Range	10% to 80% Non-Condensing	10% to 80% Non-Condensing	10% to 80% Non-Condensing
Materials	Personal Head Cap - Fabrifoam material	Personal Head Cap - Fabrifoam material	Personal Head Cap - Fabrifoam material
Biocompatibility	Materials are biocompatible	Materials are biocompatible	Materials are biocompatible
Sterility	Not Applicable	Not Applicable	Not Applicable
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.	The Brainsway DTMS System uses its own 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 60601-1 IEC 60601-1-2 IEC 62304
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.	The Brainsway DTMS System is compliant with the IEC 60601-1-2 (EMC Safety) standard.
Electrical Safety	Power Requirements: 100-240 VAC 50/60 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.	Power Requirements: 100-240 VAC 50/60 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.	The Brainsway DTMS System is compliant with the IEC 60601-1 standard.
Chemical Safety	Not Applicable	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.	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.	The Brainsway DTMS System is compliant with the IEC 60601-1-2 (EMC Safety) standard.

The modified device has the same intended use and indications for use as the Brainsway Deep TMS System cleared in 510(k) K200957. 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 (K200957), as demonstrated in the performance testing.

The modified Brainsway DTMS System incorporates the new Brainsway stimulator and minor modifications to the device cart, cooling system, coil wire and helmet. Using the new Brainsway stimulator, 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. The new stimulator and the minor modifications to the device cart, cooling system and helmet were already introduced in the reference predicate, the Brainsway DTMS System intended for treatment of OCD and cleared in 510(k) K183303.

All device modifications were tested under the design control activities, including in-house bench testing of the coil, 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 device do not pose any new safety and effectiveness concerns. Furthermore, the labeling material was revised to support the above-mentioned device modifications.

Conclusions:

Consequently, it can be concluded that the modified Brainsway Deep TMS System is substantially equivalent to the main predicate Brainsway Deep TMS System, cleared under 510(k) K200957 and the reference predicate Brainsway TMS System, cleared under 510(k) K183303. Therefore, the modified Brainsway Deep TMS System can be legally marketed in the USA.