April 23, 2021

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

Re: K203735
Trade/Device Name: Brainsway Deep TMS System (with iTBS Protocol)
Regulation Number: 21 CFR 882.5805
Regulation Name: Repetitive Transcranial Magnetic Stimulation System
Regulatory Class: Class II
Product Code: OBP
Dated: January 19, 2021
Received: January 25, 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 Scott, M.S.
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

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)*
K203735

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.

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510(K) SUMMARY

BRAINSWAY DEEP TMS SYSTEM

510(k) Number K203745

Applicant Name:
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Date Prepared: January 14, 2021

Trade Name: BrainsWay Deep TMS System (with iTBS Protocol)

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

Classification: Class II Medical Device

Predicate Device:
The subject device is a modification of the BrainsWay Deep TMS System ("reference" predicate device) that was cleared in 510(k) K122288 and the BrainsWay Deep TMS System cleared in 510(k) K173540 ("reference" predicate device). The inclusion of the iTBS stimulation protocol is substantially equivalent to the MagVita TMS Therapy System w/ Theta Burst Stimulation (Tonica Elektronik A/S, cleared in 510(k) K173620 ("main" predicate device).

Predicate	Device	Manufacturer	510(k)
Main	MagVita TMS Therapy System w/ Theta Burst Stimulation	Tonica Elektronik A/S	K173620
Secondary	BrainsWay Deep TMS System	BrainsWay Ltd.	K122288

Secondary	BrainsWay Deep TMS System	BrainsWay Ltd.	K173540

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 (H1-Coil)
    c) Cap

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 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:

The clinical performance of iTBS is dependent on the stimuli being delivered at an equal intensity, to ensure that a constant dose of stimuli is delivered during treatment. The Theta Burst Stimulation verification testing demonstrated that the intensity of the individual stimuli in iTBS stimulation protocol is equal and maintained constant throughout the delivery of the entire treatment.

Tests were conducted on the cleared BrainsWay Deep TMS Systems for the iTBS stimulation protocol 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:

The safety and effectiveness of the BrainsWay Deep Transcranial Magnetic Stimulation (TMS) device for the intended use of Major Depressive Disorder (MDD) using the intermittent theta-burst (iTBS) stimulation protocol was demonstrated in a non-inferiority analysis, comparing the iTBS treatment with the FDA cleared BrainsWay Deep TMS device to the High Frequency (HF) protocol using the same device. Following is a summary of the study.

Study Objective	The objective of the current study was to evaluate the non-inferiority of the iTBS stimulation protocol with the BrainsWay Deep TMS (H1-Coil) System compared to the FDA-cleared, High Frequency (HF) stimulation protocol using the same BrainsWay Deep TMS (H1-Coil) System, for the treatment of MDD.
Study duration	5 weeks
Number of subjects	66 subjects received iTBS stimulation protocol and 80 subjects received HF stimulation protocol.
Primary Endpoint	The primary efficacy endpoint was the change from baseline to 5 weeks visit (after 20 treatment sessions) in the patients' depression level as measured by the HDRS-21 score

Secondary Endpoints	• HDRS-21 Response Rate at 5 weeks, where response is defined as a ≥50% reduction in HDRS-21 score from baseline • HDRS-21 Remission Rate at 5 weeks, where remission is defined as HDRS-21 score < 10 • Change in CGI-S from baseline to 6 weeks • CGI-S Response Rate at 6 weeks, where response is defined as 2 point reduction in CGI-S score from baseline • CGI-S Remission Rate at 6 weeks, where remission is defined as CGI-S score ≤ 2
Intervention	iTBS stimulation protocol compared to High Frequency (HF) stimulation protocol (both stimulation protocols were delivered using the FDA cleared BrainsWay Deep TMS device).
Eligibility criteria	• Outpatients • Men and women ≥ 18 years of age (or 22-68 years of age in the multicenter MDD study) • Diagnosis of Major Depression Disorder
Study Hypothesis	**Null Hypothesis:** The mean change in HDRS-21 score from baseline at 5 weeks in the iTBS Deep TMS group is inferior to the mean change in HDRS-21 score from baseline at 5 weeks in the HF Deep TMS group, by more than 3 points. **Alternative Hypothesis:** The mean change in HDRS-21 score from baseline at 5 weeks in the iTBS Deep TMS group is inferior to the mean change in HDRS-21 score from baseline at 5 weeks in the HF Deep TMS group, by less than 3 points, i.e. is non-inferior.
Summary of Results	The non-inferiority analysis of the change from baseline between the two treatment groups was assessed. Since the upper limit of the confidence interval was less than the non-inferiority margin of 3 points, the null hypothesis of inferiority was rejected, indicating non-inferiority between the iTBS Deep TMS and HF Deep TMS treatments, when adjusted for baseline HDRS-21 scores. In summary, the change from baseline was similar between the two treatment groups at 5 weeks, which demonstrated the non-inferiority of the iTBS Deep TMS treatment.

Based on clinical results, the BrainsWay Deep TMS device with iTBS is as safe and effective as the predicate devices and enables a reduced treatment time for the benefit of both patient and operator.

Substantial Equivalence:

The following table describes the similarities and differences between the new BrainsWay Deep TMS System and the predicate devices.

TABLE 1: COMPARISON OF THE MODIFIED BRAINSWAY DEEP TMS SYSTEM TO THE CLEARED BRAINSWAY DEEP TMS SYSTEMS (K122288 & K173540) AND THE MAGVITA TMS THERAPY SYSTEM W/ THETA BURST STIMULATION (TONICA ELEKTRONIK A/S (K173620)

Technological Characteristic	**BrainsWay Deep TMS System (Models 102 & 104) with the Theta Burst stimulation protocol**	**BrainsWay Deep TMS System (Models 102 & 104) (K122288 and K173540) (Secondary Predicates)**	**MagVita TMS Therapy System w/ Theta Burst Stimulation (Tonica Elektronik A/S) (K173620) (Main Predicate)**
Product Code, Class	OBP Class II	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.	The MagVita TMS Therapy System w/ Theta Burst Stimulation is indicated for the treatment of Major Depressive Disorder in adult patients who have failed to receive satisfactory improvement from prior antidepressant medication in the current episode.
Target Population	Adult subjects with Major Depressive Disorder	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	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 Deep TMS System design is based on applying transcranial magnetic stimulation by means of repetitive pulse trains at a predetermined frequency.	The BrainsWay Deep TMS System design is based on applying transcranial magnetic stimulation by means of repetitive pulse trains at a predetermined frequency.	The MagVita System design is based on applying transcranial magnetic stimulation by means of repetitive pulse trains at a predetermined frequency.

Technological Characteristic	**BrainsWay Deep TMS System (Models 102 & 104) with the Theta Burst stimulation protocol**	**BrainsWay Deep TMS System (Models 102 & 104) (K122288 and K173540) (Secondary Predicates)**	**MagVita TMS Therapy System w/ Theta Burst Stimulation (Tonica Elektronik A/S) (K173620) (Main Predicate)**
- Mechanism of Action	The BrainsWay Deep TMS 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 Deep TMS 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 MagVita 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).
- Components	The BrainsWay Deep TMS System consists of the following components: - Mobile Cart - Coil & Helmet Unit - Positioning Arm - Cooling System - TMS stimulator & Software (BrainsWay stimulator in Model 104 & Magstim stimulator in Model 102)	The BrainsWay Deep TMS System consists of the following components: - Mobile Cart - Coil & Helmet Unit - Positioning Arm - Cooling System - TMS stimulator & Software (BrainsWay stimulator in Model 104 & Magstim stimulator in Model 102)	The MagVita System consists of the following components: - Trolley - Coil - Arm mounted on the trolley - Coil Cooler Unit - MagPro Stimulator

Technological Characteristic	**BrainsWay Deep TMS System (Models 102 & 104) with the Theta Burst stimulation protocol**	**BrainsWay Deep TMS System (Models 102 & 104) (K122288 and K173540) (Secondary Predicates)**	**MagVita TMS Therapy System w/ Theta Burst Stimulation (Tonica Elektronik A/S) (K173620) (Main Predicate)**
- Accessories	The BrainsWay Deep TMS System consists of the following accessories: - Head Cap - Head Positioning Straps - Earplugs	The BrainsWay Deep TMS System consists of the following accessories: - Head Cap - Head Positioning Straps - Earplugs	The MagVita System consists of the following accessories: - Head Cap - Holding arrangements - Marking plate, pen and ruler - Patient head fixation with treatment Chair - Vacuum Pump and Vacuum pillow
Performance	Treatment Parameters: - Magnetic Field Intensity: 120% of the patient's observed motor threshold. - Repetition rate: 50 Hz - Train duration: 2 sec - Inter-train interval: 8 sec - Burst pulses: 3 - Bursts : 200 - Number of trains: 20 - Magnetic Pulses per Session: 600 - Treatment Session Duration: approximately 3 minutes - Sessions per Week: 5 - 5 daily sessions for 4 weeks - Bi-weekly sessions for another 12 weeks (optional maintenance treatments)	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 - Burst pulses: NA - Bursts : NA - 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)	Treatment Parameters: - Magnetic Field Intensity: 120% of the patient's observed motor threshold. - Repetition rate: 50 Hz - Train duration: 2 sec - Inter-train interval: 8 sec - Burst pulses: 3 - Bursts : 200 - Number of trains: 20 - Magnetic Pulses per Session: 600 - Treatment Session Duration: approximately 3 minutes - Sessions per Week: 5 - 5 daily sessions for 6 weeks
	Waveform: Biphasic	Waveform: Biphasic	Waveform: Biphasic
	Output Stimulation Parameters: Available Stimulation Amplitude in Standard Motor Threshold (SMT) units Amplitude Range: 0.6-1.4 SMT	Output Stimulation Parameters: Available Stimulation Amplitude in Standard Motor Threshold (SMT) units Amplitude Range: 0.6-1.4 SMT	Output Stimulation Parameters: Available Stimulation Amplitude in Standard Motor Threshold (SMT) units Amplitude Range: 0 - 1.7 SMT

Technological Characteristic	BrainsWay Deep TMS System (Models 102 & 104) with the Theta Burst stimulation protocol	BrainsWay Deep TMS System (Models 102 & 104) (K122288 and K173540) (Secondary Predicates)	MagVita TMS Therapy System w/ Theta Burst Stimulation (Tonica Elektronik A/S) (K173620) (Main Predicate)
Coil Configuration Cooling	Deep TMS coil Air core Air cooling	Deep TMS coil Air core Air cooling	Figure-of-eight coil Air core Liquid cooling
Standards Met	Company complies with ISO 13485:2016	Company complies with ISO 13485:2016	Company complies with ISO 13485:2012
Electrical & EMC Safety	IEC 60601-1 IEC 60601-1-2 IEC 62304	IEC 60601-1 IEC 60601-1-2 IEC 62304	IEC 60601-1 IEC 60601-1-2

The modified device has the same intended use as the BrainsWay Deep TMS Systems cleared in 510(k) K122288 and K173540. The subject device includes a Theta Burst stimulation protocol for the same intended use. The inclusion of the iTBS stimulation protocol is substantially equivalent to the MagVita TMS Therapy System w/ Theta Burst Stimulation (Tonica Elektronik A/S, cleared in 510(k) K173620).

Both the modified device and the cleared BrainsWay Deep TMS Systems 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.

All components of the subject BrainsWay Deep TMS System are identical to the previously cleared, predicate devices 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 the same as the previously cleared BrainsWay Deep TMS Systems (K122288 and K173540). The additional non-clinical and clinical performance tests demonstrated substantial equivalence of the subject BrainsWay Deep TMS device to the predicate devices for the iTBS stimulation protocol.

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 the BrainsWay Deep TMS System, cleared under 510(k) K173540. The inclusion of the iTBS stimulation protocol is substantially equivalent to the MagVita TMS Therapy System w/ Theta Burst Stimulation (Tonica Elektronik A/S, cleared in 510(k) K173620). Therefore, the modified BrainsWay Deep TMS Systems can be legally marketed in the USA.