August 26, 2022

BrainsWay Ltd.
℅ Ahava Stein
Regulatory Consultant
A. Stein - Regulatory Affairs Consulting Ltd.
20 Hata'as Str., Suite 21
Kfar Saba, 4442518 Israel

Re: K220819
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 16, 2022
Received: March 21, 2022

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,

for 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)*
K220819

Device Name
BrainsWay Deep TMS™ System

Indications for Use *(Describe)*
The BrainsWay Deep TMS™ System is indicated for the treatment of depressive episodes and for decreasing anxiety symptoms for those who may exhibit comorbid anxiety symptoms in adult patients suffering from Major Depressive Disorder (MDD) and who failed to achieve satisfactory improvement from previous antidepressant 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 K220819

Applicant Name:
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Date Prepared: March 16, 2022

Trade Name: BrainsWay Deep TMS™ System

Common Name: Transcranial Magnetic Stimulation System

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

Classification: Class II Medical Device

Predicate Device:

The subject device is substantially equivalent to the BrainsWay Deep TMS™ Systems (Model 102 and 104) ("predicate device") cleared in 510(k) K210201 and to the reference predicate devices, the BrainsWay Deep TMS™ Systems, DEN170078 and K183303.

Predicate	Device	Manufacturer	510(k) No.
Main	BrainsWay Deep TMS™ System	BrainsWay Ltd.	K210201
Reference	BrainsWay Deep TMS™ System	BrainsWay Ltd.	K183303
Reference	BrainsWay Deep TMS™ System	BrainsWay Ltd.	DEN170078

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 to 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 (H7 Coil)
    c) Cap

The BrainsWay TMS neurostimulator is connected to the electromagnetic H7 Coil, which in turn is connected to the patient's head. The helmet aiming apparatus is used to position the BrainsWay H7 Coil at the correct position on the patient's head. The cooling system maintains the electromagnetic coil at ambient temperature. The stimulator generates a changing electric current within the coil, which induces the magnetic field. The magnetic field causes a second inductance of inverted electric charge specifically in the prefrontal cortex. Deep TMS stimulation in the area of the prefrontal cortex has been shown to be therapeutically beneficial for the following indication for use.

Intended Use/Indication for Use:

The BrainsWay Deep TMS™ System is indicated for the treatment of depressive episodes and for decreasing anxiety symptoms for those who may exhibit comorbid anxiety symptoms in adult patients suffering from Major Depressive Disorder (MDD) and who failed to achieve satisfactory improvement from previous antidepressant medication treatment in the current episode.

Performance Standards:

The 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)

- IEC 60601-1-2 Medical Electrical Equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - 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 (1999)
- ISO 10993-10 Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity (2002)
- ISO 14971 Medical devices - Application of risk management to medical devices (2nd Ed. 2007, (R) 2016)

Non-Clinical (Bench) Performance Data:

Tests were conducted on the BrainsWay Deep TMS™ System. The tests were performed 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. 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 and substantial equivalence of the BrainsWay Deep TMS™ device for the treatment of MDD and Anxiety symptoms in MDD was demonstrated in the Multicenter H7 vs H1 Study (*A Prospective Multicenter Double Blind Randomized Controlled Trial to Compare the Efficacy of the H7 Coil to H1 Coil Deep Transcranial Magnetic Stimulation (Deep TMS) in Subjects with Major Depression Disorder (MDD*)), Protocol No. CTP-0002-00. The purpose of the study was to compare the safety and effectiveness of the BrainsWay Deep TMS™ H7 Coil compared to the H1 Coil for the treatment of Major Depressive Disorder (MDD).

Baseline demographic and main effectiveness information is provided in Tables 1 and 2 below.

Table 1: Demographic Characteristics

Baseline Characteristics		% (n/N)
Sex	Male	39.1% (66/169)
	Female	60.9% (103/169)
Marital Status	Married	43.2% (73/169)
	Single	36.1% (61/169)
	Divorced	17.8% (30/169)
	Widower	3.0% (5/169)
Race	Caucasian	80.5% (136/169)
	Afro-American	6.5% (11/169)
	Hispanic	7.7% (13/169)
	Other	5.9% (10/169)
Education	Less than 9 years of education	1.2% (2/169)
	9 to 12 years of education	18.9% (32/169)
	Over 12 years of education	78.1% (132/169)
	Unknown	1.8% (3/169)
Age (years)	N	169
	Mean (SD)	45.4 (11.67)
	Median [Range]	46.6 [22.1;68.9]

Table 2 – Key Baseline Effectiveness Assessments

Safety and Effectiveness Scales		
HDRS-21	N	169
	Mean (SD)	24.0 (3.48)
	Median [Range]	24.0 [19;36]
HARS	N	168
	Mean (SD)	19.5 (6.21)
	Median [Range]	19.0 [6;43]

The primary effectiveness endpoint was the change from baseline in HDRS-21 scores to the 6-week visit. In both study groups there was a statistically significant reduction in HDRS-21 scores. The repeated measure model showed that the difference between the slopes of at 6 weeks was found non-statistically significant (p=0.8). The upper limit of the one-sided 95% CI's was 1.9, i.e., lower than 3, which is the non-inferiority limit, therefore the study is deemed successful. The response rates and the remission rates at the week 6 visit were not found statistically significantly different between the H7 and H1 Coil treatment groups.

Table 3: Difference in Change from Baseline in HDRS-21 at 6 Week Visit (Repeated Measures Model)

	Estimate	Standard Error	p-value	95% CI	Upper limit of one-sided 95% CI
Difference in Change from Baseline in HDRS-21 at 6 weeks (H7 vs H1)	0.229	1.020	0.8231	[-1.789;2.246]	1.918

According to these results, it may be concluded that the BrainsWay Deep TMS™ treatment with the H7 Coil is as effective as treatment with the H1 Coil.

There was also no statistically significant difference in the incidence of any of the adverse events reported between the treatment groups. Therefore, we can conclude that the safety of the BrainsWay Deep TMS™ device with the H7 Coil is similar to the safety with the H1 Coil.

Substantial Equivalence:

The subject BrainsWay Deep TMS™ devices (Models 102 and 104) with the H7 Coil are substantially equivalent to the previously cleared BrainsWay Deep TMS™ devices (also manufactured by BrainsWay Ltd., and the subject of 510(k) K210201 (Models 102 and 104). A comparison table is provided below comparing the intended use and basic technological characteristics of the subject BrainsWay Deep TMS™ device with the H7 Coil to the intended use and basic technological characteristics of the previously cleared BrainsWay Deep TMS™ devices. A Discussion of the Similarities and Differences between the subject BrainsWay Deep TMS™ devices with the H7 Coil and the previously cleared BrainsWay Deep TMS™ devices is found following the comparison table.

Table 4: Comparison of the BrainsWay Deep TMS™ Systems (with the H7 Coil) to the predicate BrainsWay Deep TMS™ Systems (with the H1 Coil)

Technological Characteristic	**BrainsWay Deep TMS™ Systems (Models 102 & 104 with the H7 Coil)**	**BrainsWay Deep TMS™ Systems (Models 102 & 104 with H1 Coil) (K210201)**
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 and for decreasing anxiety symptoms for those who may exhibit comorbid anxiety symptoms in adult patients suffering from Major Depressive Disorder (MDD) and who failed to achieve satisfactory improvement from previous antidepressant medication treatment in the current episode.	The BrainsWay Deep TMS™ System is indicated for the treatment of depressive episodes and for decreasing anxiety symptoms for those who may exhibit comorbid anxiety symptoms in adult patients suffering from Major Depressive Disorder (MDD) and who failed to achieve satisfactory improvement from previous antidepressant medication treatment in the current episode.

Technological Characteristic	**BrainsWay Deep TMS™ Systems (Models 102 & 104 with the H7 Coil)**	**BrainsWay Deep TMS™ Systems (Models 102 & 104 with H1 Coil) (K210201)**
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 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.
- 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).
- 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)
- 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
- Features	The BrainsWay Deep TMS™ System consists of the following features: - Determination of Motor Threshold (MT) - Coil Positioning - Administration of Treatment - System Management, including patient record keeping (Model 104)	The BrainsWay Deep TMS™ System consists of the following features: - Determination of Motor Threshold (MT) - Coil Positioning - Administration of Treatment - System Management, including patient record keeping (Model 104)
- Dimensions	Cart Dimensions: Model 102: 680x625mm / 27x25") Model 104: 680x688mm / 26.7x27"	Cart Dimensions: Model 102: 680x625mm / 27x25") Model 104: 680x688mm / 26.7x27"
- Weight	Model 102: 122.5 kg (270lbs) Model 104: 142 kg (313lbs)	Model 102: 122.5 kg (270lbs) Model 104: 142 kg (313lbs)

Technological Characteristic	BrainsWay Deep TMS™ Systems (Models 102 & 104 with the H7 Coil)	BrainsWay Deep TMS™ Systems (Models 102 & 104 with H1 Coil) (K210201)
Performance	Treatment Parameters: - Magnetic Field Intensity: 120% of the patient's observed hand motor threshold. - Repetition rate: 18 Hz - Train duration: 2 sec - Inter-train interval: 20 sec - Number of trains: 55 - Magnetic Pulses per Session: 1980 - Treatment Session Duration: ~ 20 min - 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 hand motor threshold. - Repetition rate: 18 Hz - Train duration: 2 sec - Inter-train interval: 20 sec - Number of trains: 55 - Magnetic Pulses per Session: 1980 - Treatment Session Duration: ~ 20 min - Sessions per Week: 5 - 5 daily sessions for 4 weeks - Bi-weekly sessions for another 12 weeks (optional maintenance treatments)
Human Factors	The BrainsWay Deep TMS™ System uses a TMS neurostimulator software for parameter configuration. Patient positioning and MT determination are done manually.	The BrainsWay Deep TMS™ System uses a TMS neurostimulator 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	Personal Head Cap	Personal Head Cap
Biocompatibility	Materials are biocompatible	Materials are biocompatible
Compatibility With the Environment and Other Devices	The BrainsWay Deep TMS™ System are compliant with the IEC 60601-1-2 standard.	The BrainsWay Deep TMS™ System are compliant with the IEC 60601-1-2 standard.
Sterility	Not Applicable	Not Applicable
Electrical Safety	Power Requirements: 110-120 VAC / 60 Hz 220-240 VAC / 50 Hz The BrainsWay Deep TMS™ System are compliant with the IEC 60601-1 standard.	Power Requirements: 110-120 VAC / 60 Hz 220-240 VAC / 50 Hz The BrainsWay Deep TMS™ System are compliant with the IEC 60601-1 standard.
Mechanical Safety	The BrainsWay Deep TMS™ System are compliant with the IEC 60601-1 standard.	The BrainsWay Deep TMS™ System are compliant with the IEC 60601-1 standard.
Chemical Safety	Not Applicable	Not Applicable
Thermal Safety	The BrainsWay Deep TMS™ System are compliant with the IEC 60601-1 standard.	The BrainsWay Deep TMS™ System are compliant with the IEC 60601-1 standard.
Radiation Safety	The BrainsWay Deep TMS™ System are compliant with the IEC 60601-1-2 standard.	The BrainsWay Deep TMS™ System are compliant with the IEC 60601-1-2 standard.

DISCUSSION OF SIMILARITIES AND DIFFERENCES:

The subject BrainsWay Deep TMS™ devices (Models 102 and 104) have the same intended use and indications for use as the predicate BrainsWay Deep TMS™ devices cleared in 510(k) K210201. The subject devices and the cleared BrainsWay Deep TMS™ devices are similar in terms of their intended prescription use only, suitable for adult population, indicated for the same anatomical sites, according to the same indications for use and to be used in the same hospital and/or clinic settings.

The subject BrainsWay Deep TMS™ devices have the same mechanism of operation and use the same underlying technology as the predicate BrainsWay Deep TMS™ devices. The performance characteristics, including the Output Waveform, Electrical and Magnetic Field Distribution are substantially equivalent to the previously cleared BrainsWay Deep TMS™ devices. The subject devices, as the cleared devices, introduce similar safety features and comply with same relevant consensus standards, including electrical and mechanical safety, Electromagnetic Ddisturbances, and software validation.

The subject BrainsWay Deep TMS™ devices are composed of the same device components as the previously cleared, predicate BrainsWay Deep TMS™ devices (Model 102 and Model 104), with the exception of the coil. The subject BrainsWay Deep TMS™ devices use the H7 Coil and the predicate BrainsWay Deep TMS™ devices use the H1 Coil.

This 510(k) contains clinical data to support the safety and effectiveness of the subject BrainsWay Deep TMS™ devices with the H7 Coil for the treatment of MDD. Furthermore, the clinical data demonstrates that the BrainsWay Deep TMS™ devices with the H7 Coil are substantially equivalent in performance to the predicate BrainsWay Deep TMS™ devices with the H1 Coil for the treatment of MDD. No new questions of safety and effectiveness have arisen due to the use of the new H7 Coil.

Conclusions:

Consequently, it can be concluded that the subject BrainsWay Deep TMS™ devices (Models 102 and 104) with the H7 Coil are substantially equivalent to the predicate BrainsWay Deep TMS™ devices (Models 102 and 104) with the H1 Coil, cleared under 510(k) K210201 and therefore, the modified BrainsWay Deep TMS™ System can also be legally marketed in the USA.