June 2, 2021

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

Re: K200957
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: 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 August 21, 2020. 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 12:09:08 -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

August 21, 2020

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

Re: K200957
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: July 19, 2020
Received: July 23, 2020

Dear Ms. 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

Pamela Scott
Assistant Director
DHT5B: Division of Neuromodulation
and Physical Medicine Devices
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and Physical Medicine Devices
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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)*
K200957

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.

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PRAStaff@fda.hhs.gov

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510(K) SUMMARY

THE BRAINSWAY DTMS SYSTEM

510(k) Number K200957

Applicant Name:

Company Name: **Brainsway Ltd.**
Address: 19 Hartom St. (Bynet Bldg) Har Hotzvim,
Jerusalem, 9777518, Israel.
Tel: +972 54 6420642
Fax: +972-9-7668534
E-mail: ahava@asteinrac.com

Contact Person:
Official Correspondent: Ahava Stein
Company Name: A. Stein – Regulatory Affairs Consulting Ltd.
Address: 20 Hata'as Str., Suite 102
Kfar Saba 4442520 Israel
Tel: + 972-9-7670002
Fax: +972-9-7668534
E-mail: ahava@asteinrac.com

Date Prepared: July 14, 2020

Trade Name: Brainsway DTMS System

Classification Name: CFR classification sections 882.5802;
(Product code: QMD)

Classification: Class II device.

Predicate Device:

The Brainsway DTMS System is substantially equivalent to the following predicate devices:

Predicate	Manufacturer	De Novo No.
Brainsway Ltd.	Brainsway Deep TMS System	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 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. Electromagnetic Coil
2. TMS Neurostimulator
3. Cooling System
4. Positioning System and Helmet
5. Cart

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.

Performance Standards:

The Brainsway DTMS System with the HADD-coil complies with the following recognized consensus standards:

- IEC 60601-1: 2005 (Third Edition, MOD) Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance and C1:2006 and C2:2007 and A1:2012 (or IEC60601-1:(R)2012)
- IEC 60601-1-2: Medical electrical equipment; Part 1-2: Collateral Standard: Electromagnetic compatibility - Requirements and tests, Edition 4.0 (2014).

All the requirements of these standards were met. No adaptations were made to any of the test methods recommended in the standard. There were no applied deviations from the standard. Test Certificates and reports for these tests are provided in Section 17.

Non-Clinical (Bench) Performance Data:

Bench testing was conducted for the Brainsway DTMS System and presented in Section 18. The following magnetic and electrical field characteristics and testing were conducted as proposed in the FDA Guidance document for TMS systems, Class II Special Controls Guidance Document: Repetitive Transcranial Magnetic Stimulation (rTMS) Systems:

- Electric Field Output Waveform and Linearity Measurement
- Electrical Field Spatial Distribution
- Magnetic Field Strength Gradient
- Description of the Physical Characteristics of the HADD-Coil
- Side-by-Side Comparison

Additional testing conducted with the Brainsway DTMS System included testing the life time of the device.

Pre-Clinical (Animal) Performance Data:

Not Applicable.

Clinical Performance Data:

The efficacy of the Brainsway DTMS System indicated as an aid to short-term smoking cessation has been demonstrated in a prospective, double blind, randomized, sham controlled, multi-center trial. Subjects were randomly assigned to either active DTMS or Sham treatment. TMS sessions were performed daily, five days a week, for 3 weeks (15 DTMS sessions) followed by 3 once-a-week DTMS treatments. Treatment was administered according to a predefined treatment protocol (10 Hz, 120% stimulation intensity of the measured MT, 3 sec pulse trains, 15 sec inter-train intervals, 60 trains, 1800 pulses per session). Demographic data and smoking history baseline characteristics for all the study patients in the ITT-Safety population (N=262) are presented in the tables below.

Demographic Characteristics

			DTMS	Sham
Age (years)		N	123	139

			DTMS	Sham
		Mean (SD)	45.0 (13.00)	44.8 (13.40)
		Median [Range]	46.5 [21.5;67.8]	45.8 [22.9;67.4]
Gender	Male	% (n/N)	51.2% (63/123)	52.5% (73/139)
	Female	% (n/N)	48.8% (60/123)	47.5% (66/139)
Race	Caucasian	% (n/N)	68.3% (84/123)	66.9% (93/139)
	Afro-American	% (n/N)	25.2% (31/123)	25.9% (36/139)
	Hispanic	% (n/N)	4.1% (5/123)	3.6% (5/139)
	Other	% (n/N)	2.4% (3/123)	4.3% (6/139)

Smoking History

			DTMS	Sham
Age Started Smoking (years)		N	123	139
		Mean (SD)	16.9 (3.96)	17.4 (5.35)
		Median [Range]	17.0 [8;40]	16.0 [8;41]
Total Years Smoking		N	123	139
		Mean (SD)	27.1 (13.05)	26.2 (13.73)
		Median [Range]	27.0 [4;50]	25.0 [3;62]
No. of Cigarettes / Day		N	123	139
		Mean (SD)	18.3 (7.68)	18.2 (7.21)
		Median [Range]	16.0 [10;60]	18.0 [10;50]
No. Tries to Stop	1	% (n/N)	14.3% (17/119)	21.9% (30/137)
	2	% (n/N)	10.9% (13/119)	16.1% (22/137)
	3	% (n/N)	23.5% (28/119)	18.2% (25/137)
	4	% (n/N)	11.8% (14/119)	9.5% (13/137)
	5	% (n/N)	12.6% (15/119)	7.3% (10/137)
	>5	% (n/N)	26.9% (32/119)	27.0% (37/137)
Previous Stopping Methods	Zyban	% (n/N)	12.4% (15/121)	10.1% (14/138)
	Chantix	% (n/N)	24.0% (29/121)	25.4% (35/138)
	Nicotine Patch	% (n/N)	33.9% (41/121)	35.5% (49/138)
	Nicotine Gum	% (n/N)	27.3% (33/121)	26.8% (37/138)
	Nicotine Lozenge	% (n/N)	9.1% (11/121)	10.1% (14/138)
	Nicotine Oral Inhaler	% (n/N)	5.8% (7/121)	4.3% (6/138)
	Cold Turkey	% (n/N)	73.6% (89/121)	76.8% (106/138)
	CBT or therapy	% (n/N)	3.3% (4/121)	2.9% (4/138)
	Hypnosis	% (n/N)	10.7% (13/121)	5.8% (8/138)
	Other	% (n/N)	21.5% (26/121)	18.1% (25/138)

The primary efficacy end-point, 4-week Continuous Quit Rate (CQR) was statistically significantly higher (p-value=0.0238) in the DTMS arm (17.1%) than in the sham arm (7.9%) for the ITT-Safety population, (N=262), up to 4 months follow-up. Based on the primary efficacy analysis of the study, the Brainsway DTMS has a positive treatment outcome and has demonstrated a beneficial effect in short-term smoking cessation. The higher 4-week CQR in the active DTMS arm is clinically

meaningful and statistically significant compared to the sham. Prognostic factors were assessed by adding the factors to the logistic model one at the time, except subject sex that is one of the covariates. The type III p-values were: 0.1816 for the subject sex, 0.9189 for the subject age, 0.6966 for the treatment question, 0.1238 for the age of smoking onset, and 0.7869 for the duration of smoking at baseline. None of the prognostic factors were found statistically significant. The primary efficacy endpoint of the study was substantiated by the success of the secondary endpoints including the four-week CQR in subjects with at least 4 weeks of diary records in which the CQR was statistically significantly higher (p-value=0.0071) in the DTMS arm (27.3%) compared to the sham arm (11.3%)and the number of cigarettes smoked per day (per diary entry) was statistically significantly lower in the DTMS treatment arm compared to the sham arm. . In addition, the four-week CQR up to the 6th week visit in which the CQR was statistically significantly higher (p-value=0.0022) in DTMS arm (15.4%) than in the sham arm (4.3%).There were no individual adverse event types for which a significant difference between the study groups was found, except for application site discomfort and muscle twitching. Application site discomfort did not deter subjects from receiving the treatments.

The table below presents the most common adverse events reported in the clinical study in ≥5% or more of the patients who received the Brainsway DTMS Treatment or the sham (placebo) treatment. Safety information is provided from all patients who were treated in the clinical study.

Adverse Events

	Deep TMS Treatment (N=123 Subject)		Sham Treatment (N-139 Subjects)		
Anticipated Event	No of Subjects	Incidence	No of Subjects	Incidence	p-value
Headache	30	24.39%	25	17.99%	0.2259
Application Site Discomfort	14	11.38%	3	2.16%	0.0043
Back Pain	8	6.50%	3	2.16%	0.1211
Muscle Twitching	7	5.69%	0	0%	0.0046
Discomfort	7	5.69%	2	1.44%	0.0878

The differences in any of the reported adverse events in patients who received the Brainsway DTMS Treatment compared to patients who received the sham treatment, that were statistically significant, were application site discomfort and Muscle Twitching. The most frequent AE was headache reported by 24% of the subjects who received the DTMS treatment and by 18% of the subjects who received the Sham treatment. Reporting of Headaches was not statistically significantly different

between the treatment groups. The safety and efficacy results of the Multicenter DTMS clinical study presented above demonstrate the safety and effectiveness of the Brainsway DTMS System as an aid in short-term Smoking Cessation.

Substantial Equivalence:

The Brainsway DTMS System is substantially equivalent to the previously FDA-Cleared Brainsway Deep DTMS System (also manufactured by Brainsway Ltd., and the subject of De Novo (DEN170078). The De Novo Summary for the previous Brainsway Deep TMS Systems is provided in Appendix 12-1.

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 System.

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

COMPARISON TABLE:

Technological Characteristic	Subject Device DTMS System with the HADD-coil (BRAINSWAY LTD.)	Predicate Device DTMS System (BRAINSWAY LTD.) DEN170078
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.	The Brainsway Deep Transcranial Magnetic Stimulation System is indicated for 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 Obsessive-Compulsive Disorder
Anatomical Sites	Head – stimulation to the prefrontal cortex and insula	Head – stimulation to the prefrontal cortex
Environment Used	Hospitals, Clinics	Hospitals, Clinics
Classification/ Product Code	21 CFR 882.5802/QMD	21 CFR 882.5802/QCI
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 and insula. This is a non-invasive tool for the stimulation of cortical neurons for the treatment of adult patients with smoking addiction.	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.
Area of brain to be stimulated	Prefrontal Cortex and insula	Prefrontal Cortex
System Components	The Brainsway DTMS System consists of the following components: - Mobile Cart - HADD-Coil & Helmet Unit - Positioning Arm - Cooling System - Magstim TMS stimulator	The Brainsway DTMS System consists of the following components: - Mobile Cart - HAC-Coil & Helmet Unit - Positioning Arm - Cooling System - Magstim TMS stimulator

Technological Characteristic	Subject Device DTMS System with the HADD-coil (BRAINSWAY LTD.)	Predicate Device DTMS System (BRAINSWAY LTD.) DEN170078
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
Features / Operational Procedures	- Determination of Motor Threshold (MT) - Coil Positioning - Administration of Treatment	- Determination of Motor Threshold (MT) - Coil Positioning - Administration of Treatment
Dimensions	Cart Dimensions: 680mm (L) x 625mm (W) (26.7"(L) x 24.6"(W))	Cart Dimensions: 680mm (L) x 625mm (W) (26.7"(L) x 24.6"(W))
Weight	122.5 kg (270lbs)	122.5 kg (270lbs)
Performance	Short-term Smoking Cessation Treatment Parameters: • Magnetic Field Intensity: 120% of the patient's observed motor threshold • Frequency: 10 Hz • Train Duration: 3 seconds • Inter-train interval: 15 seconds • Number of trains: 60 • Magnetic Pulses per Session: 1800 • Treatment Session Duration: ~20 min • Sessions per week: 5 daily sessions for 3 weeks, followed by 1 session per week for another 3 weeks	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: ~20 min • Sessions per week: 5 • 5 daily sessions for 5 weeks, 4 daily sessions for 1 week
Human Factors	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 the Brainsway TMS stimulator software for parameter configuration. Patient positioning and MT determination are done manually.
Standards Met	IEC 60601-1 IEC 60601-1-2	IEC 60601-1 IEC 60601-1-2
Materials	Personal Head Cap - Fabrifoam material	Personal Head Cap - Fabrifoam material
Biocompatibility	Materials are biocompatible	Materials are biocompatible
Compatibility with the Environment	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

Technological Characteristic	Subject Device DTMS System with the HADD-coil (BRAINSWAY LTD.)	Predicate Device DTMS System (BRAINSWAY LTD.) DEN170078
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 IEC 60601-1 standard.	The Brainsway DTMS System is compliant with IEC 60601-1 standard.
Chemical Safety	Not Applicable	Not Applicable
Thermal Safety	The Brainsway DTMS System is compliant with IEC 60601-1 standard.	The Brainsway DTMS System is compliant with IEC 60601-1 standard.
Radiation Safety	The Brainsway DTMS System is compliant with IEC 60601-1-2 (EMC Safety) standard.	The Brainsway DTMS System is compliant with IEC 60601-1-2 (EMC Safety) standard.

DISCUSSION OF SIMILARITIES AND DIFFERENCES:

The new Brainsway DTMS System and the predicate Brainsway DTMS System (DEN170078) are both identified under the same device classification (21 CFR 882.5802) for transcranial magnetic stimulation systems. The new Brainsway DTMS System is indicated for use as an aid in short-term smoking cessation. Heavy smoking (>10 cigarettes/day for more than 1 year) is considered an addiction, which is a psychiatric disorder or condition. The predicate device, Brainsway DTMS System (DEN170078) is intended for use as an adjunct for the treatment of adult patients suffering from OCD. Both indications for use fall under the classification regulation, 21 CFR 882.5802, for a transcranial magnetic stimulation system for neurological and psychiatric disorders and conditions.

The design and mechanism of action of the Brainsway DTMS System is similar to the design and mechanism of action of the previously cleared Brainsway DTMS System (DEN170078). The components are exactly the same, including the use of the same Magstim stimulators and the incorporation of an electromagnetic coil. Both coils are designed for effective activation of desired brain areas. The operational procedure is similar in both DTMS Systems, although the treatment stimulation parameters are different and appropriate for the relevant treatment administered. The differences in the coils, treatment stimulation parameters and resulting electromagnetic fields produced by the coils and the stimulation of the brain areas do not raise new or different questions of safety and effectiveness. Furthermore, performance testing, including the coil electrical and magnetic field distribution testing, demonstrates that the coil has output characteristics that are as safe as the predicate coil and the clinical performance testing, including the clinical results from the multicenter, Smoking Cessation clinical study, demonstrates that the coil is as effective as the predicate device in treating the specific psychiatric disorder/condition for which it is indicated to treat.

Conclusions:

In summary, the subject Brainsway DTMS System is substantially equivalent to the previous DeNovo granted predicate Brainsway DTMS System (DEN170078).