September 13, 2025

BrainsWay Ltd.
% Ahava Stein
Regulatory Consultant
A. Stein - Regulatory Affairs Consulting Ltd.
18 Hata'as Str.
Kfar Saba, 4442518
Israel

Re: K251449
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: May 9, 2025
Received: May 9, 2025

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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

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Pamela D. 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K251499

Please provide the device trade name(s).

BrainsWay Deep TMS System

Please provide your Indications for Use below.

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.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(K) SUMMARY

BRAINSWAY DEEP TMS™ SYSTEM

510(k) Number K251449

Applicant Name: **BrainsWay Ltd.**
Company Name: Dr. Colleen Hanlon, Vice President of Medical Affairs
BrainsWay Ltd

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Date Prepared: May 7, 2025

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 BrainsWay Deep TMS Systems are substantially equivalent to the following predicate devices:

Manufacturer	Device Predicates	510(k) No.	Predicate
BrainsWay Ltd.	BrainsWay Deep TMS System (Models 102 & 104)	K222196	Primary
Magnus Medical, Inc.	Magnus Neuromodulation System (MNS)	K220177	Secondary

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 (H Coil)
   c) Cap

The BrainsWay Deep TMS™ System is identical to the previously cleared BrainsWay Deep TMS™ Systems.

The purpose of this 510(k) submission is to enable modifications to the device software and expansion of the treatment stimulation protocols, to include the accelerated iTBS stimulation protocol.

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 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 Disturbances - Requirements and test (Ed 4 2014)
- IEC 62304 Medical Devices Software life-cycle processes (2006 + A1:2015)
- ISO 14971 Medical devices - Application of risk management to medical devices (2nd Ed. 2007, (R) 2016)
- ISO 10993-5 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (2009)
- ISO 10993-23 Biological evaluation of medical devices - Part 23: Tests for irritation (2021)
- ISO 10993-10 Biological evaluation of medical devices - Part 10: Tests for skin sensitization (2021)

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:

In order to support an expansion of the treatment stimulation protocols to include the accelerated iTBS stimulation protocol, clinical data was collected in a multicenter, randomized, blinded, controlled study according to the Accelerated iTBS Deep TMS Clinical Study Protocol (Protocol No. CTP-ACCiTBS-00). The study was designed as a prospective, 6 week trial, in which the accelerated iTBS (ACCiTBS) stimulation protocol was compared to the Standard of Care - High Frequency (SOC-HF) stimulation protocol.

104 subjects were enrolled and randomized into the study, of which 89 subjects, who completed the study, were included in the PP analysis set used for the primary endpoint analysis.

The subjects meeting the eligibility criteria in the study had a primary diagnosis of MDD, and had moderate or greater depression, defined as a HDRS-21 ≥20. The mean patient age was 48.6 years (ranging from 23-81 years) and 57% were female and 43% were male.

The primary effectiveness endpoint was the change in HDRS-21 scores from baseline to the 6 week visit. In both study treatment groups, there was a statistically significant

reduction in HDRS-21 scores. The adjusted mean change from baseline to 6 weeks in the AcciTBS treatment group was -19.02 points versus -19.79 in the SOC-HF treatment group. The difference between the groups of 0.77 points was not statistically significant (p=0.7783). The upper limit of the one-sided 97.5% CI of the differences between the reduction in HDRS-21 scores was lower than the non-inferiority margin and therefore the study was deemed successful.

The response rate (defined as a 50% reduction from baseline in HDRS-21 score) at 6 weeks was 87.8% [73.80%;95.92%] for the AcciTBS treatment group and 87.5% [74.75%;95.27%] for the SOC-HF treatment group. The remission rate (defined as HDRS-21 score < 10) at the week 6 visit was 78.0% [62.39%; 89.44%] for the AcciTBS treatment group and 87.5% [74.75%; 95.27%] for the SOC-HF treatment group.

Two subjects were stopped due to adverse events, including anxiety and hypomania. These two subjects were incorporated in the ITT multiple imputation sensitivity analysis using a worst-case scenario; these subjects' data were imputed with their baseline total HDRS scores. Results show that there was a statistically significant reduction in HDRS-21 scores between baseline and the 6 weeks visit within each study group, and the difference between the groups was not statistically significant. The adjusted mean change from baseline in the AcciTBS treatment group was -17.7 points at 6 weeks versus -20.11 in the SOC-HF treatment group, the difference between the groups of 2.41 points at 6 weeks (two-sided 95% Confidence interval: [-0.13, 4.95]) was not statistically significant, p=0.0626, demonstrating that the AcciTBS stimulation protocol is equivalent to the SOC-HF stimulation protocol.

For both study groups there was a significant reduction over time in the CGI-S, CGI-I, MADRS, HARS, CUDOS-D, CUXOS-D and Q-LES-Q scores. There was no significant between-group difference in the change from baseline to week 6 for all of these effectiveness assessments.

The two anxiety assessments (HARS and CUXOS-D scores) had decreases demonstrating that the accelerated iTBS treatment provides an improvement in decreasing anxiety symptoms in adult patients suffering from Major Depressive Disorder (MDD).

The adverse events reported in this study are presented above in Table 60 according to system organ class and preferred term according to the medDRA adverse event classification, for each of the study groups.

Application site discomfort and application site pain are common adverse events reported with TMS treatment and were reported in both groups. Application site discomfort occurred in 1 (1.96%) subject in the AcciTB group and in 1 (1.89%) subject in the SOC-HF group. Application site pain occurred in 4 (7.84%) subjects in the AcciTB group and in no subjects in the SOC-HF group. None of the incidents were reported as severe.

Headaches are also common adverse event reported with TMS treatment and were reported

in both groups. Headaches occurred in 21 (41.18%) subjects in the AcciTBS group and 8 (15.09%) subjects in the SOC-HF group. None of the headaches reported were classified as severe. No migraines were reported in the AcciTBS group and 2 (3.77%) subjects reported migraines in the SOC-HF group with one of the migraines being classified as severe.

As would be expected in a study with a patient population suffering from MDD, there are bound to be psychiatric disorders reported during the course of the study. Anxiety was reported in 3 (5.88%) subjects, insomnia was reported in 2 (3.92%), hypomania was reported in 1 subject, and panic attack was repored in 1 subject, of the subjects in the AcciTBS group. None of the were classified as severe.

In summary, the main adverse events typical to TMS treatment were reported with similar incidences compared to these events reported in previous clinical studies with the Brainsway Deep TMSTM device and with predicate TMS devices. In this study, there was a higher incidence of adverse events in the AcciTBS treatment group. Notably, application site pain and headaches were reported for more subjects in the AcciTBS group. The discrepancy for these particular AE's between groups is logical given the increased number and frequency of treatments for the subjects in the AcciTBS group. These findings demonstrate the overall safety of the accelerated iTBS stimulation protocol delivered with the BrainsWay Deep TMSTM System, for the treatment of Major Depressive Disorder (MDD).

The clinical study demonstrated the safety and effectiveness of the BrainsWay Deep TMS System, accelerated iTBS stimulation protocol, for treatment of Major Depressive Disorder (MDD).

Substantial Equivalence:

The subject device has the same intended use and indications for use as the primary predicate, BrainsWay Deep TMS^{TM} Systems cleared in 510(k) K222196. The subject device and the predicate devices are similar in terms of their intended prescription use only, suitable for MDD population, indicated for anatomical sites according to indications for use and to be used in hospital or clinic settings.

The subject BrainsWay Deep TMS^{TM} Systems (Models 102 and 104) are composed of the same device components as the previously cleared, predicate BrainsWay Deep TMS^{TM} Systems (Model 102 and Model 104) (K222196). The subject BrainsWay Deep TMS^{TM} Systems have the same mechanism of operation and use the same underlying technology as the predicate BrainsWay Deep TMS^{TM} Systems. The performance characteristics, including the Output Waveform, Electrical and Magnetic Field Distribution are substantially equivalent to the previously cleared BrainsWay Deep TMS^{TM} Systems. The subject devices (Models 102 and 104), as the cleared devices, have the same safety features

and comply with the same relevant consensus standards, including software validation. The subject BrainsWay Deep TMS™ device components are the same as the predicate BrainsWay Deep TMS™ device components, with the only change being the updated stimulator software, the new biocompatible materials from which the cap (worn under the helmet) is manufactured and the additional accelerated iTBS stimulation protocol. Updated software validation documents have been provided to support the software modifications. Updated biocompatibility tests have been provided demonstrating the biocompatibility of the new cap materials.

Clinical data has been provided to support the safety and effectiveness of the subject BrainsWay Deep TMS™ Systems for the treatment of MDD using the accelerated iTBS stimulation protocol. The clinical data demonstrates that the BrainsWay Deep TMS™ System using the accelerated iTBS stimulation protocol are substantially equivalent to the performance of the predicate BrainsWay Deep TMS™ Systems (using the standard of care – high frequency stimulation protocol) for the treatment of MDD and to the clinical treatment outcomes of the Magnus Neuromodulation System (K220177), which also uses an accelerated iTBS stimulation protocol. No new questions of safety and effectiveness have arisen due to the treatment in this additional patient population.

Consequently, it can be concluded that the subject BrainsWay Deep TMS™ Systems (Models 102 and 104) are substantially equivalent to the primary predicate, BrainsWay Deep TMS™ Systems, cleared under 510(k) K222196 and the clinical treatment outcomes are substantially equivalent to those reported for the secondary predicate, Magnus Neuromodulation System (K220177). The similar clinical treatment outcomes with the BrainsWay device are achieved in a method that does not require brain image-guided targeting or automation of the accelerated iTBS protocol, as in the Magnus Neuromodulation System (MNS) device.

TABLE 1: COMPARISON OF THE SUBJECT BRAINSWAY DEEP TMS™ SYSTEM TO THE CLEARED BRAINSWAY DEEP TMS™ SYSTEM (K222196)

Technological Characteristic	BrainsWay Deep TMS™ Systems (Models 102& 104)	BrainsWay Deep TMS™ Systems (Models 102 & 104) (K222196)
Product Code, Class	OBP Class II	OBP Class II
Indications for Use	The Brains Way 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 Brains Way 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.
Target Population	Adult subjects (ages 22 – 86) with Major Depressive Disorder	Adult subjects (ages 22 – 86) 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)

Technological Characteristic	BrainsWay Deep TMS™ Systems (Models 102& 104)	BrainsWay Deep TMS™ Systems (Models 102 & 104) (K222196)
- 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 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 MT - Coil Positioning - Administration of Treatment - System Management, including patient record keeping (Model 104)
- Dimensions	Cart Dimensions: Model 102: 680mm (L) x 625mm (W) (27”(L) x 25”(W)) Model 104: 680mm (L) x 688mm (W) (26.7”(L) x 27”(W))	Cart Dimensions: Model 102: 680mm (L) x 625mm (W) (27”(L) x 25”(W)) Model 104: 680mm (L) x 688mm (W) (26.7”(L) x 27”(W))
- Weight	Model 102: 122.5 kg (270lbs) Model 104: 142 kg (313lbs)	Model 102: 122.5 kg (270lbs) Model 104: 142 kg (313lbs)
Performance	Treatment Parameters SOC HF: - Magnetic Field Intensity: 120% of the patient’s observed 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: approximately 20 minutes - Sessions per Week: 5 - 5 daily sessions for 4 weeks - Bi-weekly sessions for another 12 weeks (optional maintenance treatments)	Treatment Parameters SOC HF: - Magnetic Field Intensity: 120% of the patient’s observed 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: approximately 20 minutes - Sessions per Week: 5 - 5 daily sessions for 4 weeks - Bi-weekly sessions for another 12 weeks (optional maintenance treatments)

Technological Characteristic	BrainsWay Deep TMS™ Systems (Models 102& 104)	BrainsWay Deep TMS™ Systems (Models 102 & 104) (K222196)
	Treatment Parameters iTBS: - 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 iTBS: - 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)
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 - Fabrifoam material	Personal Head Cap - Fabrifoam material
Biocompatibility	Materials are biocompatible	Materials are biocompatible
Compatibility With the Environment and Other Devices	The BrainsWay Deep TMS™ Systems are compliant with the IEC 60601-1-2 (EMC Safety) standard.	The BrainsWay Deep TMS™ Systems are compliant with the IEC 60601-1-2 (EMC Safety) standard.
Sterility	Not Applicable	Not Applicable
Electrical, Mechanical & Thermal Safety	The Brainsway DTMS Systems are compliant with the IEC 60601-1 standard.	The BrainsWay Deep TMS™ Systems are compliant with the IEC 60601-1 standard.
Chemical Safety	Not Applicable	Not Applicable
Radiation Safety	The BrainsWay Deep TMS™ Systems are compliant with the IEC 60601-1-2 (EMC Safety) standard.	The BrainsWay Deep TMS™ Systems are compliant with the IEC 60601-1-2 (EMC Safety) standard.

TABLE 2: COMPARISON OF THE BRAINSWAY DEEP TMS™ SYSTEM TO THE FDA-CLEARED MAGNUS NEUROMODULATION SYSTEM (MNS) (K220177)

Technological Characteristic	BrainsWay Deep TMS™ Systems (Models 102 & 104)	Magnus Neuromodulation System (MNS) (K220177)
Product Code, Class	OBP Class II	OBP Class II
Indications for Use	The Brains Way 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 Magnus Neuromodulation System with Saint Technology is indicated for the treatment of Major Depressive Disorder (MDD) in adult patients who have failed to achieve satisfactory improvement from prior antidepressant medication in the current episode.
Performance	Treatment Parameters Accelerated iTBS: - Magnetic Field Intensity: 110% of the patient's observed motor threshold. - Repetition rate: 50 Hz - Burst pulses: 3 - Train duration: 2 sec - Inter-train interval: 8 sec - Magnetic Pulses per Session: 1,800 - Treatment Session Duration: approximately 10 minutes - 5 sessions per day for 6 days (over a 14 day period), followed by 2 treatment sessions per day once a week for 4 weeks - Total treatment pulses: 68,400 - Treatment duration: 6 weeks -Target: Standard H1 positioning	Treatment Parameters Accelerated iTBS: - Magnetic Field Intensity: 90% of the patient's observed motor threshold, adjusted for scalp to cortex distance. - Repetition rate: 50 Hz - Burst pulses: 3 - Train duration: 2 sec - Inter-train interval: 8 sec - Magnetic Pulses per Session: 1,800 - Treatment Session Duration: approximately 10 minutes - 10 sessions per day for 5 consecutive days. No further treatment sessions. - 50 sessions per week - Total treatment pulses: 90,000 - Treatment duration: 5 days - Target: Functional MRI-guided targeting, customized to the patient

Conclusions:

The subject BrainsWay Deep TMS™ Systems (Models 102 and 104) are substantially equivalent to the BrainsWay Deep TMS™ Systems cleared under 510(k) K222196 and have substantially equivalent clinical treatment outcomes to the Magnus Neuromodulation System (K220177) and therefore, the modified BrainsWay Deep TMS™ System may be legally marketed in the USA.