



November 7, 2025

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

Re: K251391
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: October 9, 2025
Received: October 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,


Heather L. Dean -S

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

Indications for Use

510(k) Number (if known)
K251391

Device Name
BrainsWay Deep TMS System

Indications for Use (Describe)

The BrainsWay Deep TMS TM 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 TM System is also indicated as an adjunct for the treatment of Major Depressive Disorder (MDD) in adolescent patients (age 15-21 years).

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 K251391

Applicant Name:

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

Address:

BrainsWay Ltd.
16 Hartom St.
Har Hotzvim, Jerusalem, ISRAEL 9777516 Tel: +972-2-5813140
Fax: +972-2-5812517
E-mail: ahava@asteinrac.com

Contact Person:

Official Correspondent: Ahava Stein

Company Name: A. Stein – Regulatory Affairs Consulting Ltd. Address:
18 Hata'as Str., Suite 21
Kfar Saba 4442518 Israel Tel: + 972-9-7670002
Fax: +972-9-7668534
E-mail: ahava@asteinrac.com

Date Prepared: April 30, 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 subject device is a substantially equivalent to the BrainsWay Deep TMS™ Systems (Model 102 and 104) cleared in 510(k) K222196 and to the NeuroStar Advanced Therapy System cleared in 510(k) K231926.

Device	Manufacturer	510(k) No.
BrainsWay Deep TMS™ System	BrainsWay Ltd.	K210201
NeuroStar Advanced Therapy System	Neuronetics Inc.	K231926

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 for use as an adjunct for the treatment of Major Depressive Disorder (MDD) in adolescent patients (age 15-21 years).

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.

The BrainsWay Deep TMS™ System is also indicated as an adjunct for the treatment of Major Depressive Disorder (MDD) in adolescent patients (age 15-21 years).

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 patient population who may be treated with the BrainsWay Deep TMS™ device to adolescent subjects (15- 21 years old), clinical data has been collected from subjects treated by commercial users of the device, i.e., from Real World Data (RWD). The RWD has been accrued according to the procedures outlined in a pre-defined Clinical Study Protocol (Protocol No. RWD-MDDAdol-01).

The RWD data for the study analysis consisted of 1,120 adolescent patients (age 15-21) who received the BrainsWay standard of care high frequency or iTBS treatment protocol for MDD between 2012 and 2024. The RWD was collected from 35 TMS centers in the

US. Efficacy was analyzed based on an improvement from baseline in depression outcomes, using the PHQ-9 assessment score, at the end of 6 weeks of BrainsWay Deep TMS treatment, according to the following study hypothesis:

H0: $P \leq 50\%$

The proportion of subjects who meet the success criteria defined as a decrease of at least 5 points on the PHQ-9 assessment scale at the end of treatment is less than or equal to 50%

H1: $P > 50\%$

The proportion of subjects who meet the success criteria defined as a decrease of at least 5 points on the PHQ-9 assessment scale at the end of treatment is greater than 50%

An additional 319 adolescent patients in the BrainsWay database were not included in the ITT analysis set as they were screen failures who did not meet the study eligibility criteria. There were no significant differences found between the screen failures and the ITT analysis set, when average age, gender distribution, race/ethnicity, site and geographical location of the sites were compared.

The following eligibility criteria set forth in the study protocol were adhered to, when determining the subjects included in the ITT analysis set.

Inclusion Criteria

- Outpatients.
- Male or female subjects 15 - 21 years of age.
- Subjects with a primary diagnosis of Major Depressive Disorder (MDD), according to DSM-4/ICD-9 or DSM-5/ICD-19 criteria, as applicable on the date treatment with BrainsWay Deep TMS™ therapy began.
- Subjects with a pre-treatment Patient Health Questionnaire-9 (PHQ-9) score of ≥ 10 or an HDRS-21 score of >14 , indicating moderate or greater depression.
- Subjects with PHQ-9 scores available at pre-Deep TMS treatment evaluation (defined as the closest score available within 7 days prior to administration of the first treatment) and at post-Deep TMS treatment evaluation (defined as the closest score available within ± 7 days of the date of the last treatment).
- Subjects received a course of at least 20 treatments with the BrainsWay Deep TMS™ device to the left dorsolateral prefrontal cortex (DLPFC), consisting of the FDA-cleared, high frequency or iTBS stimulation protocol.
- Treatment start date on or after January 1, 2012 and treatment end date on or before the date on which the retrospective study sample is extracted from the BrainsWay Registry database.

Exclusion Criteria

- Gap in BrainsWay Deep TMS™ treatment of > 14 continuous days.

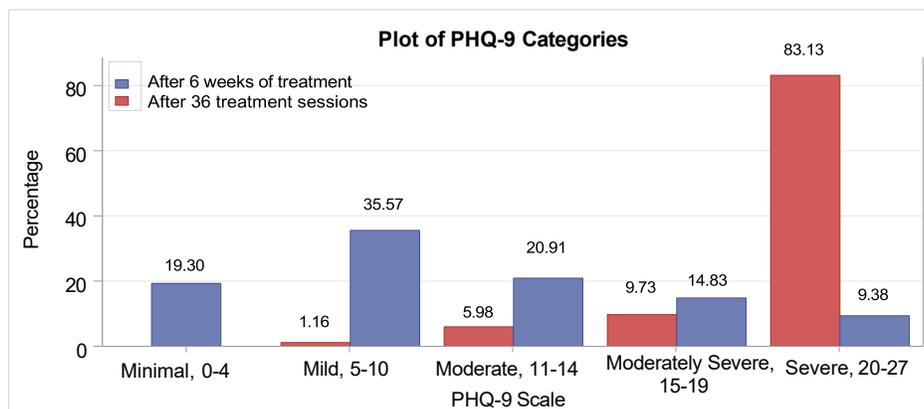
The subjects meeting the eligibility criteria in the study had a primary diagnosis of MDD, had received at least 20 treatments with the BrainsWay Deep TMS device to the dorsolateral prefrontal cortex (DLPFC) and had moderate or greater depression, defined as a Physician Health Questionnaire-9 (PHQ-9) score ≥ 10 . The mean patient age was 19.4 years (ranging from 15-21 years) and 63% were female.

The co-primary endpoints were defined as the proportion of subjects who met the Individual Success Criteria and the change from baseline in PHQ-9 scores at the end of treatment (defined as after 6 weeks of treatment). The following results are presented for the Per Protocol analysis set defined as “all subjects in the study who met the study eligibility criteria, including receiving at least 20 treatments with BrainsWay Deep TMS device (without a gap more than 14 continuous days). The co-primary endpoints were met as 80.9% (95% CI: 78.5%, 83.2%) of this analysis population met the Individual Subject Success Criteria, with the lower limit of the 95% confidence interval exceeding the pre-established Overall Study Success Criteria of a minimum 50% by 30.9%. This proportion was found to be statistically significant at $p < 0.001$. The mean change in PHQ-9 scores from baseline to the end of treatment was -10.3 ± 6.2 [95% CI; $-10.66, -9.93$] and was also found to be statistically significant ($p < 0.001$).

The co-primary endpoints were also analyzed wherein "end of treatment" was defined as after 36 treatment sessions (rather than 6 weeks). In this scenario, the co-primary endpoints were met as well. 87.8% (95% CI: 85.7%, 89.7%) of this analysis population met the Individual Subject Success Criteria, with the lower limit of the 95% confidence interval exceeding the pre-established Overall Study Success Criteria of a minimum 50% by 37.8%. This proportion was found to be statistically significant at $p < 0.001$. The mean change in PHQ-9 scores from baseline to the end of treatment was -12.1 ± 6.15 [95% CI; $-12.47, 11.74$] and was also found to be statistically significant ($p < 0.001$).

The response rate at the end of treatment (wherein response is defined as a $\geq 50\%$ reduction in PHQ-9 score from baseline) was 54.4% after 6 weeks of treatment and 66.1% after 36 treatment sessions. The remission rate at the end of treatment (wherein remission is defined as a PHQ-9 score < 5) was 19.3% after 6 weeks of treatment and 30% after 36 treatment sessions.

A graphical representation of the change in PHQ-9 category of depression severity from baseline to post-treatment is provided in Figure 1 below.



Substantial Equivalence:

The subject device has the same intended use and indications for use as the FDA-cleared Neurostar System (K231926), including the expanded adolescent MDD patient population, and the FDA-cleared BrainsWay Deep TMS™ Systems (K222196). The subject device and the predicate devices are similar in terms of their intended prescription use only, suitable for adult and adolescent populations, indicated for anatomical sites according to indications for use and to be used in hospital or clinic settings.

The subject BrainsWay Deep TMS™ Systems are composed of the same device components as the previously cleared, predicate BrainsWay Deep TMS™ Systems (Model 102 and Model 104) (K222196). The subject BrainsWay Deep TMS™ Systems have the same mechanism of operation and use the same underlying technology as the predicate BrainsWay Deep TMS™ Systems. The performance characteristics, including the Output Waveform, Electrical and Magnetic Field Distribution are substantially equivalent to the previously cleared BrainsWay Deep TMS™ Systems. The subject devices, as the cleared devices, have the same safety features and comply with same relevant consensus standards, including software validation. Updated software validation documents have been provided to support the software modifications.

Performance testing has been provided to support the expanded indications for use of adolescents (15-21 years) with MDD and is provided in the relevant section of this 510(k).

The clinical data demonstrates that the BrainsWay Deep TMS™ Systems are substantially equivalent to the performance of the predicate BrainsWay Deep TMS™ Systems for the treatment of MDD. No new questions of safety and efficacy have arisen due to the treatment in this additional patient population.

TABLE 1: COMPARISON OF THE BRAINSWAY DEEP TMS™ SYSTEM TO THE FDA-CLEARED NEUROSTAR SYSTEM (K231926)

Technological Characteristic	BrainsWay Deep TMS™ Systems (Models 102 & 104)	Neurostar System (K231926)
Product Code, Class	OBP Class II	OBP Class II
Indications for Use	<p>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.</p> <p>The BrainsWay Deep TMS™ System is also indicated as an adjunct for the treatment of Major Depressive Disorder (MDD) in adolescent patients (age 15-21 years).</p>	<p>NeuroStar Advanced Therapy is indicated as an adjunct for the treatment of Major Depressive Disorder (MDD) in adolescent patients (age 15-21).</p>

TABLE 2: 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	<p>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.</p> <p>The BrainsWay Deep TMS™ System is also indicated as an adjunct for the treatment of Major Depressive Disorder (MDD) in adolescent patients (age 15-21 years).</p>	<p>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.</p>
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).

Technological Characteristic	BrainsWay Deep TMS™ Systems (Models 102& 104)	BrainsWay Deep TMS™ Systems (Models 102 & 104) (K222196)
- Components	The BrainsWay Deep TMS™ System consists of the following components: <ul style="list-style-type: none"> - 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: <ul style="list-style-type: none"> - 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: <ul style="list-style-type: none"> - Head Cap - Head Positioning Straps - Earplugs 	The BrainsWay Deep TMS™ System consists of the following accessories: <ul style="list-style-type: none"> - Head Cap - Head Positioning Straps - Earplugs
- Features	The BrainsWay Deep TMS™ System consists of the following features: <ul style="list-style-type: none"> - 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: <ul style="list-style-type: none"> - 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: <ul style="list-style-type: none"> - 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: <ul style="list-style-type: none"> - 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)
	<p>Treatment Parameters iTBS:</p> <ul style="list-style-type: none"> - 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) 	<p>Treatment Parameters iTBS:</p> <ul style="list-style-type: none"> - 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	<p>The BrainsWay Deep TMS™ System uses a TMS neurostimulator software for parameter configuration. Patient positioning and MT determination are done manually.</p>	<p>The BrainsWay Deep TMS™ System uses a TMS neurostimulator software for parameter configuration. Patient positioning and MT determination are done manually.</p>
Standards Met	<p>IEC 60601-1 IEC 60601-1-2 IEC 62304</p>	<p>IEC 60601-1 IEC 60601-1-2 IEC 62304</p>
Materials	<p>Personal Head Cap - Fabrifoam material</p>	<p>Personal Head Cap - Fabrifoam material</p>
Biocompatibility	<p>Materials are biocompatible</p>	<p>Materials are biocompatible</p>
Compatibility With the Environment and Other Devices	<p>The BrainsWay Deep TMS™ Systems are compliant with the IEC 60601-1-2 (EMC Safety) standard.</p>	<p>The BrainsWay Deep TMS™ Systems are compliant with the IEC 60601-1-2 (EMC Safety) standard.</p>
Sterility	<p>Not Applicable</p>	<p>Not Applicable</p>
Electrical, Mechanical & Thermal Safety	<p>The Brainsway DTMS Systems are compliant with the IEC 60601-1 standard.</p>	<p>The BrainsWay Deep TMS™ Systems are compliant with the IEC 60601-1 standard.</p>
Chemical Safety	<p>Not Applicable</p>	<p>Not Applicable</p>
Radiation Safety	<p>The BrainsWay Deep TMS™ Systems are compliant with the IEC 60601-1-2 (EMC Safety) standard.</p>	<p>The BrainsWay Deep TMS™ Systems are compliant with the IEC 60601-1-2 (EMC Safety) standard.</p>

Conclusions:

The subject BrainsWay Deep TMS™ Systems (Models 102 and 104) are substantially equivalent to the Neurostar System (K231926) and to the BrainsWay Deep TMS™ Systems cleared under 510(k) K222196 and therefore, the modified BrainsWay Deep TMS™ System may be legally marketed in the USA.