January 13, 2023

Magstim Company Ltd
Tom Campbell
Corporate Director Regulatory Affairs
Spring Gardens
Whitland, Carmarthenshire SA340HR
United Kingdom

Re: K222171
Trade/Device Name: Magstim Horizon 3.0 TMS Therapy System, Horizon 3.0 System, Horizon 3.0, H3.0, Horizon 3.0 with StimGuide+
Regulation Number: 21 CFR 882.5805, 21 CFR 882.5802
Regulation Name: Repetitive Transcranial Magnetic Stimulation System
Regulatory Class: Class II
Product Code: OBP, QCI
Dated: December 13, 2022
Received: December 14, 2022

Dear Tom Campbell:

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

Digitally signed by Pamela D. Scott -S
Date: 2023.01.13 22:31:45 -05'00'

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

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)*
K222171

Device Name
Horizon 3.0 TMS Therapy System

Indications for Use *(Describe)*
Horizon 3.0 TMS Therapy System is indicated for the treatment of Major Depressive Disorder in adult patients who have failed to achieve satisfactory improvement from prior antidepressant medication in the current episode, as well as an adjunct for the treatment of adult patients suffering from Obsessive-Compulsive Disorder (OCD).

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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K222171
Traditional 510(k) SUMMARY
Magstim's Horizon® 3.0 TMS Therapy System

Prepared according to the requirements outlined in 21 CFR 807.92

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Magstim® Company Limited
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Contact Person: Tom Campbell, Corporate Director Regulatory Affairs

Date Prepared: August 31, 2022

Trade Name of Device

Horizon® 3.0 TMS Therapy System

Common or Usual Name

Transcranial Magnetic Stimulation System for Neurological and Psychiatric Disorders and Conditions

Classification

21 C.F.R. § 882.5805, Class II, product code OBP
21 C.F.R. § 882.5802, Class II, product code QCI

Predicate Devices

K212289 NeuroStar Advanced Therapy, Neuronetics Inc. *(Primary Predicate Device)*, 21 C.F.R § 882.5802, QCI
K211389 Horizon® 3.0 TMS Therapy System, The Magstim® Company Limited *(Secondary Predicate Device)*, 21 C.F.R § 882.5805, OBP
K193006 MagVenture TMS Therapy, Tonica Elektronik A/S *(Reference Predicate),* 21 C.F.R § 882.5802, QCI

Device Description

The Horizon® 3.0 TMS Therapy System is a computerized, electromechanical medical device that produces and delivers non-invasive, magnetic stimulation using brief duration rapidly alternating, or pulsed, magnetic fields to induce electrical currents directed at spatially discrete regions of the cerebral cortex. This method of cortical stimulation by application of brief magnetic pulses to the head is known as Transcranial Magnetic Stimulation. ("TMS").

The Horizon® 3.0 TMS Therapy System is a non-invasive tool for the stimulation of cortical neurons for the treatment of Major Depressive Disorder (MDD) in adult patients who have failed to achieve satisfactory improvement from antidepressant medication in the current

episode, as well as an adjunct for the treatment of adult patients suffering from Obsessive-Compulsive Disorder (OCD).

The Horizon® 3.0 TMS Therapy System is used for patient treatment by prescription only under the supervision of a licensed physician. It can be used in both inpatient and outpatient settings, including physicians' offices, clinics, and hospitals.

Horizon® 3.0 TMS Therapy System is an integrated system consisting of a combination of hardware, software, and accessories. Its technological characteristics are described in further detail below.

Intended Use & Indications for Use

The Horizon® 3.0 TMS Therapy System is intended to produce and deliver non-invasive, magnetic stimulation using brief duration rapidly alternating, or pulsed, magnetic fields to induce electrical currents directed at spatially discrete regions of the cerebral cortex.

Horizon® 3.0 TMS Therapy System is indicated for the treatment of Major Depressive Disorder in adult patients who have failed to achieve satisfactory improvement from prior antidepressant medication in the current episode, as well as an adjunct for the treatment of adult patients suffering from Obsessive-Compulsive Disorder (OCD).

Technological Characteristics

Horizon® 3.0 TMS Therapy System and its technological characteristics remain almost identical to that cleared within K211389.

The proposed changes to Horizon 3.0, for adjunctive treatment of OCD, are limited to updates to the IFU and software for user interface and treatment stimulation parameters. Both these changes are made to facilitate safe and effective treatment of patients with OCD and do not raise new or different questions of safety and effectiveness.

The coil positioning mechanism of action with Horizon 3.0 also remains unchanged with two options available dependent on Horizon 3.0 configuration. Horizon 3.0 with StimGuide+ offers the ability to locate and determine MT and the location of the treatment location with the use of stereotactic navigation, where standard Horizon 3.0 uses the conventional manual measurement approach.

All other aspects of the device compared to the currently marketed Horizon 3.0 device remain unchanged and are identical.

Non-clinical Testing

Due to the minor nature of changes to the current Horizon 3.0 device, only a limited amount of non-clinical testing was necessary:

1. Software verification & validation of the Horizon 3.0 software updates. The software modification was performed in accordance with IEC 62304 and the company's quality procedure, which is considered a well-established method via the utilization of a recognized international standard (FR Recognition Number 13-79) and the utilization of the development strategy used in the software development of the most recently cleared Horizon 3.0 device (K211389).
2. Performance verification of the system therapeutic delivery. Testing was performed to verify that Horizon 3.0 could reliably and safely deliver the OCD protocol, at maximum output whilst remaining within recognized safety temperature limits. The verification protocol and test limits are well-established methods via utilization of a recognized international standard (FR Recognition Number 19-46) for the safety limits and K182853 for the verification protocol.
    a. In addition to OCD protocol performance testing, the subject device (Horizon 3.0) and the primary predicate device (NeuroStar) applicating coils were modeled in COMSOL and according to Finite Element Method (FEM) and statistical analysis, the induced E-field profiles are equivalent and have an average difference of ±5% at distances of 1 to 4 cm from the coil surface. The data provided is consistent with the FDA's guidance "Class II Special Controls Guidance Document: Repetitive Transcranial Magnetic Stimulation (rTMS)."
3. Human Factors testing of user interface and coil positioning mechanism was performed in accordance with HE 75 and IEC 62366 and the company's quality procedure, which is considered a well-established method via the utilization of a recognized international standard (FR Recognition Number 5-57 and 5-114) and the utilization of the validation strategies used in the development of the most recently cleared Horizon 3.0 device (K211389).

The testing performed is both described in the software section **(Section XVIII)** and performance testing section **(Section XX).**

No further testing for Electrical Safety, Mechanical Safety, Electromagnetic Compatibility, Alarm Systems and Biocompatibility was necessary as previous data submitted as part of K211389 premarket notification remains valid to demonstrate safety and effectiveness and support a determination of substantial equivalence. This is re-iterated in **Sections XII, XIV, XVII and XIX.**

Substantial Equivalence

Horizon 3.0 device changes are limited to updates to the IFU and software for user interface and treatment stimulation parameters. Both these changes are made to facilitate safe and effective treatment of patients with OCD and do not raise new or different questions of safety and effectiveness. Information on these changes can be found in the software section, **Section XVIII.**

Where the labelling has been updated, this has been performed appropriately to identify various contraindications and instructions relevant to the usage of the device for treatment of

OCD as per special controls. Confirmed to be equivalent to that of the reference predicate (K193006), the well-established method used to update the labeling to extend the indication to include OCD does not raise new or different questions regarding safety and effectiveness. Labelling can be found in **Section XV.**

The focus component of both the subject device and the primary predicate device when considering the extension to the indication to include OCD is the stimulating coil.

Whilst the coil construction characteristics of the Ez Cool Coil and the NeuroStar Advanced Therapy are different, the magnetic field characteristics of the coils are equivalent which is pertinent to treatment delivery effectiveness. Earlier in K143531, the FDA determined that Magstim figure of eight stimulating coils are substantially equivalent to the NeuroStar Advanced Therapy System coil for the treatment of Major Depressive Disorder in adult patients who have failed to achieve satisfactory improvement from medication in the current episode. This decision was later further substantiated in a retrospective open-label study titled "Comparative Efficacy of Repetitive Transcranial Magnetic Stimulation for Treatment of Depression Using 2 Different Stimulation Devices: A Retrospective Open-Label Study" where the authors Oliveira-Maia, Garcia-Guarniz, et al, conclude in that there was no statistically significant differences between outcomes in Magstim and NeuroStar treated patients which is suggestive of equivalent antidepressant efficacy between devices.[1]

To further substantiate this argument, the Horizon 3.0 Ez Cool Coil and the NeuroStar Advanced Therapy Coil were modeled in COMSOL and according to the finite element modelling (FEM) and statistical analysis, the induced E-field profiles by the Horizon 3.0 Ez Cool Coil and NeuroStar Advanced Therapy Coil are equivalent and have an average difference of ±5% at distances of 1 to 4 cm from the coil surface. The modeling method is based on well-established scientific methods, equivalent to those used to demonstrate equivalence for the reference predicate (K193006). For further information on the modelling, please refer to **Section XX.**

Coil positioning mechanism is identical to that of the Primary Predicate (K211389) where non-clinical testing according to international standard IEC 62366-1 (5-114) and HE 75 (5-57) has demonstrated that representative TMS users, after a brief training session, were able to appropriately position the coil for treatment, and follow the recommended treatment definition protocol with low variability between position. Human factors testing information can be found in **Section XX.**

Thus, in summary, as an adjunct for the treatment of OCD, the Horizon 3.0 figure of eight stimulating coil is considered equivalent to the NeuroStar Advanced Therapy System coil cleared by the FDA in K212289 and does not raise new or different questions of safety and effectiveness.

All other aspects of the device compared to the currently marketed Horizon 3.0 device remain unchanged and are identical.

Conclusion

[1] *(Garcia-Guarniz AL, Sinanis A, Pascual-Leone A, Press D. Comparative efficacy of repetitive transcranial magnetic stimulation for treatment of depression using 2 different stimulation devices: A retrospective open-label study. J Clin Psychiatry 2016;77:e743.)*

In summary, the intended use and indications for use for Horizon 3.0 and it predicate devices are identical.

The minor modifications to Horizon 3.0 to extend the indications for use do not raise new or different questions regarding safety and effectiveness. Where non-clinical testing was performed, this was performed according to well established methods recognized either as an FDA recognized standard, FDA guidance document, scientific literature or via an approach previously accepted by the FDA.

Although the indications have been modified, the overall operating principles of TMS devices for stimulating the cerebral cortex remains the same. Regardless of indication, the same type of energy output is used and the same principles apply to determining a MT hotspot and positioning of the coil for delivery of brief duration, rapidly alternating, or pulsed, magnetic fields to induce electrical currents that are directed at spatially discrete regions of the cerebral cortex. The Physical State, Technical Method and Target Area for both OBP and QCI devices are equivalent in themselves.

Non-clinical test data collected via well-established methods demonstrates that Horizon 3.0 is as safe and effective as its predicate devices (K211389 and K212289).

Thus, the information and data provided in this 510(k) premarket notification submission support a finding of substantial equivalence for the Horizon 3.0 for the treatment of Major Depressive Disorder in adult patients who have failed to achieve satisfactory improvement from prior antidepressant medication in the current episode, as well as an adjunct for the treatment of adult patients suffering from Obsessive-Compulsive Disorder (OCD).

A tabular comparison of device characteristics can be found on the following page.

Criteria	**Horizon 3.0 TMS Therapy System** (Subject of this submission)	**HORIZON 3.0 TMS Therapy System** (K211389) *(Secondary Predicate)*	**NeuroStar Advanced Therapy System** (K212289) (*Primary Predicate*)	**Magventure TMS Therapy System** (K193006) (*Reference Predicate*)
Manufacturer	Magstim Company Limited	Magstim Company Limited	Neuronetics, Inc.	Tonica Elektronik A/S
Device Name	Horizon 3.0 TMS Therapy System	Horizon 3.0 TMS Therapy System	NeuroStar TMS Therapy System	Magventure TMS Therapy System
Clearance date		09/14/2021	05/06/2022	08/09/2020
510(k) number	K222171	K211389	K212289	K193006
Device code	OBP, QCI	OBP	QCI	QCI
Intended Use/ Indications for Use	The Horizon 3.0 TMS Therapy System is indicated for the treatment of Major Depressive Disorder in adult patients who have failed to receive satisfactory improvement from prior antidepressant medication in the current episode, as well as an adjunct for the treatment of adult patients suffering from Obsessive-Compulsive Disorder (OCD).	The Horizon 3.0 TMS Therapy System is indicated for the treatment of Major Depressive Disorder in adult patients who have failed to receive satisfactory improvement from prior antidepressant medication in the current episode.	The NeuroStar Advanced Therapy System is intended to be used as an adjunct for the treatment of adult patients suffering from Obsessive-Compulsive Disorder (OCD).	The MagVenture TMS Therapy System is intended to be used as an adjunct for the treatment of adult patients suffering from Obsessive-Compulsive Disorder (OCD).
OCD Treatment Protocol				
Magnetic Field Intensity	100% of the MT	N/A	100% of the MT	100% of the MT
Stimulus Frequency	20 Hz	N/A	20 Hz	20 Hz
Stimulus Train duration	2 sec	N/A	2 sec	2 sec
Inter-train interval	20 sec	N/A	20 sec	20 sec
Number of trains	50	N/A	50	50

Magnetic Pulses per Session	2000	N/A	2000	2000
Treatment Session Duration	18.3 min	N/A	18.3 min	18.0 min
Sessions/week	5	N/A	5	5
Treatment Schedule	5 daily sessions for 5 weeks, 4 daily sessions for 1 week.	N/A	5 daily sessions for 5 weeks, 4 daily sessions for 1 week.	5 daily sessions for 5 weeks, 4 daily sessions for 1 week.
Area of brain to be stimulated	Dorsomedial Prefrontal Cortex	N/A	Dorsomedial Prefrontal Cortex	Dorsomedial Prefrontal Cortex
Standard Treatment Protocol				
Magnetic Field Intensity	120% of the MT	120% of the MT	N/A	N/A
Stimulus Frequency	10 Hz	10 Hz	N/A	N/A
Stimulus Train duration	4 sec	4 sec	N/A	N/A
Inter-train interval	11-26 sec	11-26 sec	N/A	N/A
Number of trains	75	75	N/A	N/A
Magnetic Pulses per Session	3000	3000	N/A	N/A
Treatment Session Duration	18.8 min–37.5 min	18.8 min–37.5 min	N/A	N/A
Sessions/week	5	5	N/A	N/A
Treatment Schedule	5 daily sessions for 6 weeks	5 daily sessions for 6 weeks	N/A	N/A
Area of brain to be stimulated	Left Dorsolateral Prefrontal Cortex	Left Dorsolateral Prefrontal Cortex	N/A	N/A
iTBS Treatment Protocol				
Stimulation Intensity	120% of the MT	120% of the MT	N/A	N/A
Repetition Rate	50 Hz (5 pulses per sec)	50 Hz (5 pulses per sec)	N/A	N/A

Train Duration	2 sec			2 sec			N/A	N/A
Inter-train Interval	8 sec			8 sec			N/A	N/A
Burst Pulses	3			3			N/A	N/A
Bursts	200			200			N/A	N/A
Inter Pulse interval	20 msec			20 msec			N/A	N/A
Number of trains	20			20			N/A	N/A
Number of Pulses per Session	600			600			N/A	N/A
Treatment Session Duration	3.09 min			3.09 min			N/A	N/A
Sessions/week	5			5			N/A	N/A
Treatment Schedule	5 daily sessions for 6 weeks			5 daily sessions for 6 weeks			N/A	N/A
Area of brain to be stimulated	Left Dorsolateral Prefrontal Cortex			Left Dorsolateral Prefrontal Cortex			N/A	N/A
	Horizon® MT Remote Coil	Horizon® 3.0 E-z Cool Coil	Horizon® 3.0 E-z Cool Coil (Nav)	Horizon® MT Remote Coil	Horizon® 3.0 E-z Cool Coil	Horizon® 3.0 E-z Cool Coil (Nav)	NeuroStar Stimulating Coil	Cool D-B80
Waveform	Biphasic	Biphasic	Biphasic	Biphasic	Biphasic	Biphasic	Biphasic	Biphasic
Core Material	Air	Air	Air	Air	Air	Air	Ferromagnetic Core	Air, Liquid Cooled
Pulse Width	330µs	340µs	340µs	330µs	340µs	340µs	180µs	290µs
Amplitude in SMT units (Standard Motor Threshold)	0.28 - 1.9			0.28 - 1.9			0.22 – 2.08	0 – 1.9

Frequency range (Hz) at 100%	1 – 20	1 - 20	0.1 - 30	0.1 - 30
Pulse train duration range (sec)	0.1 – 600	0.1 - 600	1-20	Unknown
Inter-train interval range (sec)	1 – 540	1 - 540	10-60	Unknown
Maximum # of pulses per session (cumulative exposure)	60000	60000	5000	Unknown
Maximum output amplitude (V/m) at a depth of 2cm below the coil surface	150 V/m	150 V/m	135 V/m nominal	Unknown
Maximum magnetic field strength (T) at coil surface	1.0T	1.0T	0.7T	1.0T
Maximum magnetic field strength (T) at a depth of 2cm	0.4T	0.4T	0.5T	Unknown
Maximum magnetic field gradient (dB/dt) (kT/s) at coil surface	18 kT/s	18 kT/s	27 kT/s	31 kT/s
Maximum magnetic field gradient (dB/dt) (kT/s) at a depth of 2cm	10 kT/s	10 kT/s	11 kT/s	11 kT/s
Coil Positioning and MT Determination Principle for OCD				

System Configuration	Horizon 3.0	Horizon 3.0 with StimGuide+	Horizon 3.0	Horizon 3.0 with StimGuide+	NeuroStar Advanced Therapy System	MagVenture TMS Therapy System
Coil Position Principle for OCD	Indirect targeting of treatment target through measured distance and direction (4cm anterior) from Leg MT Hotspot. Measure derived from statistical distance of DMPFC/ACC from MT hotspot.	Indirect targeting of treatment target through measured distance and direction (4cm) from Leg MT Hotspot using stereotactic navigation. Measure derived from statistical distance of DMPFC/ACC from MT hotspot.	N/A		Indirect targeting of treatment target through measured distance and direction (4cm anterior) from Leg MT Hotspot using contact sensing and head support system. Measure derived from statistical distance of DMPFC/ACC from MT hotspot.	Indirect targeting of treatment target through measured distance and direction (4cm anterior) from Leg MT Hotspot using contact sensing and head support system. Measure derived from statistical distance of DMPFC/ACC from MT hotspot.
MT Response Principle for OCD	Visual qualitative monitoring for APB response		N/A		Visual qualitative monitoring for APB response	Visual qualitative monitoring for APB response
Coil Positioning and MT Determination Principle for MDD						
Coil Position Principle for MDD	**Horizon 3.0**	**Horizon 3.0 with StimGuide+**	**Horizon 3.0**	**Horizon 3.0 with StimGuide+**	**NeuroStar Advanced Therapy System**	**MagVenture TMS Therapy System**
Coil Position Principle for MDD	Indirect targeting of treatment target through measured distance and direction (5.5cm) from MT Hotspot. Measure derived from statistical distance of DLPFC from MT hotspot.	Indirect targeting of treatment target through measured distance and direction (5.5cm) from MT Hotspot using stereotactic navigation. Measure derived from statistical distance of DLPFC	Indirect targeting of treatment target through measured distance and direction (5.5cm) from MT Hotspot. Measure derived from statistical distance of DLPFC from MT	Indirect targeting of treatment target through measured distance and direction (5.5cm) from MT Hotspot using stereotactic navigation. Measure derived from	N/A	N/A