November 10, 2017

Nexstim Plc
Jarmo Laine
Vice President, Medical Affairs
Elimaenkatu 9b
Helsinki, 00510 Finland

Re: K171902
Trade/Device Name: Nexstim Navigated Brain Therapy (NBT) System 2
Regulation Number: 21 CFR 882.5805
Regulation Name: Repetitive Transcranial Magnetic Stimulation System
Regulatory Class: Class II
Product Code: OBP, GWF, HAW, IKN
Dated: October 11, 2017
Received: October 12, 2017

Dear Jarmo Laine:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

William J. Heetderks -S
2017.11.10 09:28:53 -05'00'

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K171902

Device Name
Nexstim Navigated Brain Therapy (NBT) System 2

Indications for Use *(Describe)*
Nexstim Navigated Brain Therapy (NBT) System 2 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.

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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510(k) Summary

Submission Date: 01 October 2017

Submitter:
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Manufacturing Site:
Nexstim Plc
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00510 Helsinki, Finland

Trade Name: Nexstim Navigated Brain Therapy (NBT®) System 2

Classification Name: Repetitive Transcranial Magnetic Stimulator For Treatment Of Major Depressive Disorder

Primary Classification Regulation and Product Code: 21 CFR §882.5805 / OBP

Secondary Classification Regulation and Product Code:
21 CFR §882.1870 / GWF
21 CFR §882.4560 / HAW
21 CFR §890.1375 / IKN

Substantially Equivalent Devices:

New Model	*Predicate 510(k) Number*	*Predicate Manufacturer / Model*
Nexstim Navigated Brain Therapy (NBT®) System 2	K143531	Magstim Company Limited / Rapid^2 Therapy System (Primary Predicate)
	K112881	Nexstim Oy / Nexstim Navigated Brain Stimulation (NBS) System 4, Nexstim NBS System with NexSpeech™ (Reference Predicate)
	K162935	Magstim Company Limited / Rapid^2 Therapy System (Reference Predicate)
	K133408	Neuronetics, Inc. Neurostar TMS Therapy System (Reference Predicate)
	K150641	Tonica Elektronik A/S / MagVita TMS Therapy System (Reference Predicate)

510(k) Summary

Device Description: The Nexstim NBT® System 2 is a repetitive transcranial magnetic stimulation (rTMS) system that delivers repetitive pulsed magnetic fields of sufficient magnitude to induce neural action potentials in the prefrontal cortex to treat the symptoms of major depressive disorder (MDD) without inducing seizure in patients who have failed one antidepressant medication.

The Nexstim NBT System 2 is used for patient treatment by prescription only and must be operated by a trained medical professional. It can be used in both inpatient and outpatient settings including physician's offices and clinics, psychiatric hospitals, and general medical/surgical hospitals with psychiatric units.

The Nexstim NBT System 2 consists of a group of devices designed to localize the stimulation site in the brain and deliver rTMS stimulation using controlling and interpretive software. Operational control of the Nexstim NBT System 2 is provided by the software.

The Nexstim NBT System 2 combines magnetic resonance imaging-based (MRI-based), three-dimensional (3-D) localization of cortical motor areas of the brain with non-invasive TMS and simultaneous electromyography (EMG) measurement to locate areas of the brain that are capable of evoking muscle responses when stimulated, and to locate the target area for depression therapy.

The Nexstim NBT System 2 software is used to import a patient's MR image slices through standard DICOM communication protocols, and generates an accurate 3-D model of the patient's head which can be "peeled back" to reveal the anatomical structures of the brain.

Intended Use: Nexstim Navigated Brain Therapy (NBT®) System 2 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.

510(k) Summary

Technology Comparison:

The Nexstim NBT System 2 employs the same technological characteristics as the predicate devices.

Characteristic	***Magstim Company Limited Rapid² Therapy System (K143531)*** ***(Primary Predicate)***	***Nexstim Oy NBS System 4 with NEXSPEECH™ (K112881)*** ***(Reference Predicate)***	***Nexstim Navigated Brain Therapy (NBT®) System 2 (Proposed Device)***
Magnetic Field Intensity	120 % of motor threshold (MT)	Not applicable	120 % of MT
Frequency	10 Hz	Not applicable	10 Hz
Train Duration	4 seconds (sec)	Not applicable	4 sec
Inter-train Interval	26 sec	Not applicable	26 sec
Number of trains	75	Not applicable	75
Maximum pulses per session	3,000	Not applicable	3,000
Treatment session duration	~ 37.5 minutes	Not applicable	~ 37.5 minutes
Sessions/week	Five (5)	Not applicable	Five (5)
Treatment schedule	Five (5) daily sessions for six (6) weeks	Not applicable	Five (5) daily sessions for six (6) weeks
Area of brain to be stimulated	Dorsolateral Prefrontal cortex (DLPFC)	Language areas	DLPFC
Coil Material	Copper winding with air core	Copper winding with air core	Copper winding with air core
Coil Windings	70 mm N = 3 x 19 turns /wing x 2 wings (1.75 mm x 6 mm)	72 mm (coil wing distance 2 mm, coil wind center distance 74 mm) 10 turns/wing	72 mm (coil wing distance 2 mm, coil wind center distance 74 mm) 10 turns/wing
Average Inductance	12 µH	10.4 µH	10.4 µH

Characteristic (continued)	***Magstim Company Limited Rapid² Therapy System (K143531)*** ***(Primary Predicate)***	***Nexstim Oy NBS System 4 with NEXSPEECH™ (K112881)*** ***(Reference Predicate)***	***Nexstim Navigated Brain Therapy (NBT®) System 2 (Proposed Device)***
Amplitude Range	0.28 to 1.9 Standard MT (SMT)	0 to 2.5 SMT	0 to 2.5 SMT
Pulse Length	300 µsec	230 µs ± 5 µsec	230 µs ± 5 µsec
Frequency Range	0.1 - 30 Hz	0.1 - 50 Hz	0.1 - 50 Hz
Coil Positioning Principle	Indirect targeting of treatment target though measured distance and direction (5cm) from Abductor Pollicis Brevis (APB). Measure derived from statistical distance of DLPFC from APB.	Individual patient direct targeting of anatomical treatment location (Language areas). Placing of E-field maximum location on 3D model built from patients individual MRI.	Individual patient direct targeting of anatomical treatment location (DLPFC). Placing of E-field maximum location on 3D model built from patients individual MRI.
MT Response Detection	Visual qualitative monitoring for APB response.	EMG provides qualitative and quantitative data based on which user defines MT.	EMG provides qualitative and quantitative data based on which user defines MT.

Summary of Performance Testing:

Sterilization and Shelf Life Verification

The Nexstim NBT System 2 is not shipped sterile, and is not intended to be sterilized by the user.

The NBT Head Tracker has a shelf life of 2 years.

The Nexstim Focal and Cooled Coils have a useful product life of two (2) million pulses or two (2) years from date of manufacture, whichever comes first.

No other Nexstim NBT System 2 component has a shelf life.

510(k) Summary

Biocompatibility Verification

Patient contact materials which are part of the Nexstim NBT System 2 were designed to comply with the following standard:

- *ISO 10993-1: 2009, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process,*

and were determined to be safe to use with patients.

Software Verification and Validation

Software for the Nexstim NBT System 2 was designed and developed according to a robust software development process, and were rigorously verified and validated.

Software information is provided in accordance with internal documentation and the following Standards and guidance documents:

- *FDA guidance: The content of premarket submissions for software contained in medical devices, 11 May 05;*
- *FDA guidance: Off-the-shelf software use in medical devices, 09 Sep 99;*
- *FDA guidance: General principles of software validation; Final guidance for industry and FDA staff, 11 Jan 02;*
- *FDA guidance: Content of premarket submissions for management of cybersecurity in medical devices, 02 Oct 14.*
- *FDA guidance: Cybersecurity for Networked Medical Devices Containing Off-The-Shelf (OTS) software, 14 Jan 05; and*
- *IEC 62304: 2006, Medical device software – Software life cycle processes.*

Test results indicate that the Nexstim NBT System 2 software complies with its predetermined specifications, and the Standards and guidance documents.

Electrical Safety Verification

The Nexstim NBT System 2 was tested for performance in accordance with the following Standards:

- *IEC 60601-1: 2005, Am1: 2012, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance; and*
- *ANSI/AAMI ES 60601-1: 2005, Am2: 2010, US National differences to IEC 60601-1: 2005.*

Test results indicated that the Nexstim NBT System 2 complies with the Standards.

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Electromagnetic Compatibility (EMC) Verification

The Nexstim NBT System 2 was tested for performance in accordance with the following Standard:

- *IEC 60601-1-2: 2007, Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests; and*
- *FCC 47 CFR §15, Telecommunication Chapter I--Federal Communications Commission Subchapter A—General- Radio Frequency Devices*

Test results indicated that the Nexstim NBT System 2 complies with the Standards.

Performance Testing – Bench Verification

The Nexstim NBT System 2 was tested for performance in accordance with internal documentation and the following FDA Guidance Documents and Standards:

- *Guidance for Industry and Food and Drug Administration Staff Class II Special Controls Guidance Document: Repetitive Transcranial Magnetic Stimulation (rTMS) Systems*
- *Study Comparing Nexstim's Electromyography-Determined Motor Threshold (MT) Method to the Manually-Determined MT Method (O'Reardon, 2007; Pridmore, 1998) Demonstrating No Significant Statistical Difference Between Methods*
- *Study Comparing Nexstim's Navigated Coil Localization Method to Manually-Determined Method (moving the coil 5.5 cm anteriorly from the motor cortex, Ahdab, 2010) Demonstrating Substantially Equivalent Results Between Methods*

Test results indicated that the Nexstim NBT System 2 complies with its predetermined specification and the applicable Standard.

Performance Testing – Usability Validation

The Nexstim NBT System 2 was tested for usability in accordance with the following Standards:

- *IEC 60601-1-6: 2010, Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability; and*
- *IEC 62366: 2007, Medical devices – Application of usability engineering to medical devices.*

Test results indicated that the Nexstim NBT System 2 complies with the applicable Standards.

510(k) Summary

Conclusion

Verification and validation activities were conducted to establish the performance and safety characteristics of the Nexstim NBT System 2. The results of these activities demonstrate that the Nexstim NBT System 2 is safe and effective when used in accordance with its intended use and labeling.

Therefore, the Nexstim NBT System 2 is considered substantially equivalent to the predicate devices.