March 20, 2026

Nexstim Oyj
Jarmo Laine
Vice President, Medical Affairs
Elimäenkatu 9b
Helsinki, 00510
Finland

Re: K253098
Trade/Device Name: Nexstim Navigated Brain Stimulation (NBS) 6 System (NBS6)
Regulation Number: 21 CFR 882.5805
Regulation Name: Repetitive transcranial magnetic stimulation system
Regulatory Class: Class II
Product Code: OBP, QCI, GWF, IKN, QFF
Dated: February 18, 2026
Received: February 18, 2026

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 (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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 and Part 809); 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 Management System Regulation (QMSR) (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,

ROBERT KANG -S

for 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.	K253098

Please provide the device trade name(s).

Nexstim Navigated Brain Stimulation (NBS) 6 System (NBS6)

Please provide your Indications for Use below.

The Nexstim Navigated Brain Stimulation (NBS) 6 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).

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

- [x] Prescription Use (Part 21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

provided in accordance with 21 CFR §807.92(c)

510(k) Number:	K253098
Submission Date:	18 March 2026
Submitter:	Nexstim Oyj Elimäenkatu 9b 00510 Helsinki, Finland
Submitter and Official Contact:	Mr. Jarmo Laine Vice President, Medical Affairs Jarmo.Laine@nexstim.com +011 358 (9) 2727 170
Manufacturing Site:	Nexstim Oyj Elimäenkatu 9b 00510 Helsinki, Finland
Trade Name:	Nexstim Navigated Brain Stimulation (NBS) 6 System
Classification Name:	Repetitive Transcranial Magnetic Stimulator For Treatment Of Major Depressive Disorder
Primary Regulation and Product Code:	21 CFR §882.5805 / OBP
Secondary Regulation and Product Code:	21 CFR §882.5802 / QCI 21 CFR §882.1870 / GWF 21 CFR §882.5805 / QFF 21 CFR §890.1375 / IKN

Predicate and Reference Devices:

New Model	Primary Predicate 510(k) Number	Primary Predicate Manufacturer / Model
Nexstim Navigated Brain Stimulation (NBS) 6 System	K241518	Horizon® 3.0 TMS Therapy System (Horizon 3.0 Inspire); Horizon® 3.0 TMS Therapy System (Horizon 3.0 with StimGuide Pro); Horizon® 3.0 TMS Therapy System (Horizon 3.0)
	Reference Devices 510(k) Numbers	**Reference Devices Manufacturer / Models**
	K182700	Nexstim, Plc / Nexstim Navigated Brain Therapy (NBT) System 2
	K171902	Nexstim, Plc / Nexstim NBT System 2
	K182768	Axilum Robotics / TMS-Cobot TS MV

510(k) Summary

provided in accordance with 21 CFR §807.92(c)

Device Description:

The Nexstim NBS 6 System is a non-invasive, 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 depressive episodes without inducing seizure in adult patients with Major Depressive Disorder (MDD) who have failed antidepressant medication, as well as to provide adjunct treatment to adult patients suffering from Obsessive Compulsive Disorder (OCD).

The Nexstim NBS 6 System 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 NBS 6 System 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 NBS 6 System is provided by the software.

The Nexstim NBS 6 System combines magnetic resonance imaging-based (MRI-based), three dimensional (3D) 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 areas for treatment of MDD and adjunct treatment of OCD.

The software used in the Nexstim NBS 6 System is essentially the same software used in the Reference device Nexstim NBT System 2 cleared by FDA in 510(k) submissions K171902 and K182700 except for a new workflow-oriented graphical user interface (GUI) designed for improved ease of use. This GUI is new to the Nexstim NBS 6 System, and allows the user to select which functionality the software will present, including:

- Access to the same functions as in NBT System 2 for:
  - MDD (K171902),
  - MDD with the Intermittent Theta Burst Stimulation (iTBS) Protocol (K182700), and
- Access to functions for NBS 6 System (proposed device) for adjunct treatment of OCD.

Indications for Use:

The Nexstim Navigated Brain Stimulation (NBS) 6 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).

510(k) Summary

provided in accordance with 21 CFR §807.92(c)

Technology Comparison	The Nexstim NBS 6 System employs the same technological characteristics as the predicate device(s).		
Characteristic	***Nexstim NBS 6 System (This Submission)*** ***Subject device***	***Horizon® 3.0 TMS Therapy System (Horizon 3.0 Inspire); Horizon® 3.0 TMS TherapySystem (Horizon 3.0 with StimGuide Pro); Horizon® 3.0 TMS Therapy System (Horizon 3.0) (K241518)*** ***Primary Predicate***	***Substantial Equivalence Discussion***
Indications for use (IFU) statement	The Nexstim Navigated Brain Stimulation (NBS) 6 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).	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).	The subject device IFU is the same as primary predicate except for the product name.
Primary regulation(s) / product code(s)	21 CFR §882.5805 / OBP	21 CFR §882.5805 / OBP	Same.
Secondary regulation(s) / product code(s)	21 CFR §882.5802 / QCI 21 CFR §882.1870 / GWF 21 CFR §890.1375 / IKN 21 CFR §882.5805 / QFF	21 CFR §882.5802 / QCI	The subject device has the same QCI product code as the primary predicate. The GWF and IKN product codes are the same as the Nexstim NBT System 2 (K171902 and K182700) reference devices addressing evoked stimulus and EMG functions in addition to rTMS and iTBS. The stereotaxis product code HAW was removed and replaced with QFF. The reference device for this product code is the Axilum Robotics TMS-Cobot TS MV (K182768), which has the same indications for use as the arm that supports the Nexstim coil as an electromechanical arm for a transcranial magnetic stimulation system.
Area of brain to be stimulated	Dorsomedial Prefrontal Cortex (DMPFC) for OCD. Left Dorsolateral Prefrontal Cortex (DLPFC) for MDD.	DMPFC for OCD. DLPFC for MDD.	Same.

510(k) Summary

provided in accordance with 21 CFR §807.92(c)

Technology Comparison	The Nexstim NBS 6 System employs the same technological characteristics as the predicate device(s).		
Characteristic	***Nexstim NBS 6 System (This Submission)*** ***Subject device***	***Horizon® 3.0 TMS Therapy System (Horizon 3.0 Inspire); Horizon® 3.0 TMS TherapySystem (Horizon 3.0 with StimGuide Pro); Horizon® 3.0 TMS Therapy System (Horizon 3.0) (K241518)*** ***Primary Predicate***	***Substantial Equivalence Discussion***
Clinical data submitted to support depression treatment, specifically anxious depression.	No.	No.	Clinical data were not necessary to support substantial equivalence to the primary predicate based upon the equivalence of the primary predicate treatment coils and its predicate treatment coils in K241518. The subject device coils are demonstrated to be equivalent to the primary predicate treatment coil based on comparison of magnetic and electrical field testing. The proposed device is sufficiently similar to the predicate device in terms of indications, device specifications, and energy output such that reliance on bench testing is sufficient to demonstrate substantial equivalence. The bench testing, as outlined in the TMS guidance document, "Repetitive Transcranial Magnetic Stimulation (rTMS) Systems - Class II Special Controls Guidance for Industry and FDA Staff" was conducted and compared to the predicate device and found to be substantially equivalent. The differences identified during testing do not raise questions of safety or effectiveness
Treatment Protocols			
Standard MDD Treatment			
Area of brain to be stimulated	Left Dorsolateral Prefrontal Cortex (DLPFC)	Left Dorsolateral Prefrontal Cortex (DLPFC)	Same.
Magnetic field intensity	120 % of MT	120 % of MT	Same.
Frequency	10 Hz	10 Hz	Same.
Train duration	4 seconds	4 seconds	Same.
Inter-train interval	11-26 seconds	11-26 seconds	Same.
Number of trains	75	75	Same.
Maximum pulses per session	3000	3000	Same.
Treatment session duration	19-37.5 minutes	19-37.5 minutes	Same.
Sessions/week	Five (5)	Five (5)	Same.
Treatment schedule	Five (5) daily sessions for six (6) weeks	Five (5) daily sessions for six (6) weeks	Same.

510(k) Summary
provided in accordance with 21 CFR §807.92(c)

Technology Comparison	The Nexstim NBS 6 System employs the same technological characteristics as the predicate device(s).		
Characteristic	***Nexstim NBS 6 System (This Submission)*** ***Subject device***	***Horizon® 3.0 TMS Therapy System (Horizon 3.0 Inspire); Horizon® 3.0 TMS TherapySystem (Horizon 3.0 with StimGuide Pro); Horizon® 3.0 TMS Therapy System (Horizon 3.0) (K241518)*** ***Primary Predicate***	***Substantial Equivalence Discussion***
iTBS for MDD			
Area of brain to be stimulated	Left Dorsolateral Prefrontal Cortex (DLPFC)	Left Dorsolateral Prefrontal Cortex (DLPFC)	Same.
Magnetic field intensity	120 % of MT	120 % of MT	Same.
Frequency	50Hz (50 pulses per sec)	50Hz (50 pulses per sec)	Same.
Train duration	2 secs	2 secs	Same.
Inter-train interval	Inter-train interval: 8 secs Burst pulses: 3 Bursts: 200 Inter-pulse interval: 20 msec	Inter-train interval: 8 secs Burst pulses: 3 Bursts: 200 Inter-pulse interval: 20 msec	Same.
Number of trains	20	20	Same.
Maximum pulses per session	600	600	Same.
Treatment session duration	3 min, 9 secs	3 min, 9 secs	Same.
Sessions/week	5	5	Same.
Treatment schedule	Five (5) daily sessions for six (6) weeks	Five (5) daily sessions for six (6) weeks	Same.
OCD Treatment			
Area of brain to be stimulated	Dorsomedial Prefrontal Cortex (DMPFC)	Dorsomedial Prefrontal Cortex (DMPFC)	Same.
Magnetic field intensity	100 % of MT	100 % of MT	Same.
Frequency	20 Hz	20 Hz	Same.
Train duration	2 seconds	2 seconds	Same.
Inter-train interval	20 seconds	20 seconds	Same.
Number of trains	50	50	Same.
Maximum pulses per session	2000	2000	Same.

510(k) Summary
provided in accordance with 21 CFR §807.92(c)

Technology Comparison	The Nexstim NBS 6 System employs the same technological characteristics as the predicate device(s).		
Characteristic	***Nexstim NBS 6 System (This Submission)*** ***Subject device***	***Horizon® 3.0 TMS Therapy System (Horizon 3.0 Inspire); Horizon® 3.0 TMS TherapySystem (Horizon 3.0 with StimGuide Pro); Horizon® 3.0 TMS Therapy System (Horizon 3.0) (K241518)*** ***Primary Predicate***	***Substantial Equivalence Discussion***
Treatment session duration	18.3 minutes	18.3 minutes	Same.
Sessions/week	Five (5)	Five (5)	Same.
Treatment schedule	Five (5) daily sessions for five (5) weeks; four (4) daily sessions for one (1) week.	Five (5) daily sessions for five (5) weeks; four (4) daily sessions for one (1) week.	Same.
Coil Positioning System			
Coil positioning principle	Individual patient direct targeting of anatomical treatment location (DLPFC) for MDD. Indirect targeting of treatment target through measured distance and direction for OCD: 4.0cm from MT Hotspot using stereotactic navigation. Measure derived from statistical distance from MT hotspot. Placing of E-field maximum location on 3D model built from patients individual MRI. The therapy target is set by trained physician at the known anatomical location of the DLPFC or the measured distance of DMPFC from MT hotspot on the 3D model of patient's individual anatomy. Nexstim bases its coil positioning and orientation relative to the patient's head on highly accurate stereotactic navigation. During the treatment sequence the coil is held by a mechanical arm that is locked in place when the system identifies that the e-field maximum is on the desired treatment position. The correctness of the placement position and orientation of the coil is continuously monitored by the system to ensure that the treatment stimulations are delivered to the right spot with optimal orientation.	<u>Horizon 3.0</u> Indirect targeting of treatment target through measured distance and direction (4.0cm for OCD; 5.5cm for MDD) from MT Hotspot. Measure derived from statistical distance of DLPFC from MT hotspot. <u>Horizon 3.0 with Stimguide +</u> Indirect targeting of treatment target through measured distance and direction (4.0cm for OCD; 5.5cm for MDD) from MT Hotspot using stereotactic navigation. Measure derived from statistical distance of DLPFC from MT hotspot.	The subject device is the same as the primary predicate for OCD. The subject device is the same as the Nexstim NBT System 2 (K171902 and K182700) reference devices for MDD.
Tracking system method	Polaris Vicra® optical sensor integrated into the cart.	Optical sensor for stereotactic navigation	The subject device is the same as the Nexstim NBT System 2 (K171902 and K182700) reference devices for the tracking system method.

510(k) Summary

provided in accordance with 21 CFR §807.92(c)

Technology Comparison	The Nexstim NBS 6 System employs the same technological characteristics as the predicate device(s).		
Characteristic	***Nexstim NBS 6 System (This Submission)*** ***Subject device***	***Horizon® 3.0 TMS Therapy System (Horizon 3.0 Inspire); Horizon® 3.0 TMS TherapySystem (Horizon 3.0 with StimGuide Pro); Horizon® 3.0 TMS Therapy System (Horizon 3.0) (K241518)*** ***Primary Predicate***	***Substantial Equivalence Discussion***
TMS Stimulation			
Modes	Repetitive TMS.	Repetitive TMS	Same.
Method	Magnetic field pulses that penetrate the skull and induce a stimulating electric field in the brain tissue.	Magnetic field pulses that penetrate the skull and induce a stimulating electric field in the brain tissue	Same.
MT response detection	EMG provides qualitative and quantitative data based on which user defines MT. Option 2: Visual qualitative monitoring for TA response (OCD).	Option 1: EMG provides quantitative data based on which user defines MT. Option 2: Visual qualitative monitoring for APB response (MDD) or for TA response (OCD).	The subject device is the same as the primary predicate Option 1 and Option 2 for OCD treatment.
Applicator (TMS II Focal Coil)			
Shape	Figure 8-shaped coil with forced air cooling.	Figure 8-shaped coil with forced air cooling.	Same.
Diameter	Coil windings: 72 mm (coil wing distance 2 mm, coil wind center distance 74 mm) Average inductance: 10.4 µH Flat spiral winding: 10 turns/wing	Coil windings: 70 mm Average inductance: 12 µH Flat spiral winding: N = 3 x 19 turns/wing x 2 wings (1.75 mm x 6 mm)	The subject device is the same as the Nexstim NBT System 2 (K171902 and K182700) reference devices for the focal coil diameter.
Core material	Copper winding with air core	Copper winding with air core	Same.
Stimulation Parameters			
Maximum output amplitude	2.5 SMT Maximum electric field 220 V/m at 20 mm and 172 at 25 mm depth below the coil in spherical conductor model representing the human head, 10 cm in diameter.	1.9 Standard Motor Threshold (SMT) 150 V/m at 20 mm below coil surface	The subject device is the same as the Nexstim NBT System 2 (K171902 and K182700) reference devices for the maximum output amplitude. The subject device covers full range of the primary predicate and has an identical range as the reference devices. As output is calibrated to the patient's individual MT level, the difference is that the subject device can cover a broader range of patients.

510(k) Summary

provided in accordance with 21 CFR §807.92(c)

Technology Comparison	The Nexstim NBS 6 System employs the same technological characteristics as the predicate device(s).		
Characteristic	***Nexstim NBS 6 System (This Submission)*** ***Subject device***	***Horizon® 3.0 TMS Therapy System (Horizon 3.0 Inspire); Horizon® 3.0 TMS TherapySystem (Horizon 3.0 with StimGuide Pro); Horizon® 3.0 TMS Therapy System (Horizon 3.0) (K241518)*** ***Primary Predicate***	***Substantial Equivalence Discussion***
Maximum magnetic field strength	Maximum field at different depths directly below coil. 1.31 T (6.5 mm) 1.09 T (10 mm) 0.81 T (15 mm) 0.61 T (20 mm) 0.45 T (25 mm)	1.0 T (surface of the coil) 0.4 T (20 mm)	The subject device is the same as the Nexstim NBT System 2 (K171902 and K182700) reference devices for the maximum magnetic field strength.
Current waveform	Biphasic sinusoid	Biphasic sinusoid	Same.
Pulse length and rise time	230 µs ± 5 µs, 58 µs	340 µs	The subject device is the same as the Nexstim NBT System 2 (K171902 and K182700) reference devices for the pulse length and rise time. The treatment protocol always requires the definition of the individual MT of each patient. Therefore, the output of the device is calibrated to the individual patient so that the effect is achieved with the minimum dose. Although the pulse length and rise time of the reference devices are different than the primary predicate, the output used to treat the patient is similar due to the calibration to MT. Therefore, the devices are the same with respect to treating patients.
Frequency range	0.1 - 50 Hz (includes iTBS)	1-50Hz (includes iTBS) 1-20Hz at 100 % stimulator intensity	The subject device covers the primary predicate stimulation frequency range. The subject device is the same as the Nexstim NBT System 2 (K171902 and K182700) reference devices for the frequency.

510(k) Summary

provided in accordance with 21 CFR §807.92(c)

Summary of Performance Testing:

Sterilization and Shelf Life Verification	The Nexstim NBS 6 System is not shipped sterile and is not intended to be sterilized by the user. The NBS 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 NBS 6 System component has a shelf life.
Biocompatibility Verification	Patient contact materials which are part of the Nexstim NBS 6 System 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, Cybersecurity, and Interoperability	Software for the Nexstim NBS 6 System was designed and developed according to a robust software development process and was rigorously verified and validated. Software information is provided in accordance with internal documentation and the following guidance documents and Standard: • *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, 27 Sep 19.* • *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.* • *FDA guidance: Cybersecurity in medical devices: Quality system considerations and content of premarket submissions, 27 Jun 25.* • *FDA guidance: Postmarket management of cybersecurity in medical devices, 22 Jan 16.* • *FDA guidance: Design considerations and pre-market submission recommendations for interoperable medical devices, 06 Sep 17.* • *IEC 62304: 2006, Am1: 2015, Medical device software – Software life cycle processes.* Test results indicate that the Nexstim NBS 6 System software complies with its predetermined specifications, and the guidance documents and Standard.

510(k) Summary

provided in accordance with 21 CFR §807.92(c)

Electrical Safety Verification

The Nexstim NBS 6 System 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.*
- *ANSI/AAMI ES 60601-1: 2005, Am2: 2010, US National differences to IEC 60601-1: 2005.*

Test results indicated that the Nexstim NBS 6 System complies with the Standards.

Electromagnetic Compatibility (EMC) Verification

The Nexstim NBS 6 System was tested for performance in accordance with the following guidance document and Standards:

- *FDA guidance: Electromagnetic Compatibility (EMC) of Medical Devices, 06 Jun 22.*
- *IEC 60601-1-2: 2014, Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests.*
- *FCC 47 CFR §15, Telecommunication Chapter I--Federal Communications Commission Subchapter A—General- Radio Frequency Devices.*

Test results indicated that the Nexstim NBS 6 System complies with the guidance document and Standards.

Performance Testing – Bench Verification

The Nexstim NBS 6 System was tested for performance in accordance with internal documentation and the following FDA guidance document:

- *FDA guidance: Guidance for Industry and Food and Drug Administration Staff Class II Special Controls Guidance Document: Repetitive Transcranial Magnetic Stimulation (rTMS) Systems, 26 Jul 11.*

Test results indicated that the Nexstim NBS 6 System complies with its predetermined specification and the guidance document.

Performance Testing – Usability Validation

The Nexstim NBS 6 System was tested for usability in accordance with the following guidance document and Standards:

- *FDA guidance: Applying human factors and usability engineering to medical devices, 03 Feb 16.*
- *IEC 60601-1-6: 2010, Am1: 2013, Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability.*
- *IEC 62366: 2007, Medical devices – Application of usability engineering to medical devices.*

Test results indicated that the Nexstim NBS 6 System complies with the guidance document and Standards.

510(k) Summary

provided in accordance with 21 CFR §807.92(c)

Clinical performance testing	No clinical testing was necessary.
Conclusion	Verification and validation activities were conducted to establish the performance and safety characteristics of the Nexstim NBS 6 System. The results of these activities demonstrate that the Nexstim NBS 6 System is as safe, as effective, and performs as well as the predicate devices. Therefore, the Nexstim NBS 6 System is considered substantially equivalent to the predicate devices.