April 8, 2022

Eemagine Medical Imaging Solutions GmbH
% Gary Syring
Principal Consultant
Quality & Regulatory Associates, LLC
800 Levanger Lane
Stoughton, Wisconsin 53589

Re: K210109
Trade/Device Name: visor2 system
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: HAW, GWF, IKN, OBP
Dated: March 9, 2022
Received: March 11, 2022

Dear Gary Syring:

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 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)*
K210109

Device Name
visor2 system

Indications for Use *(Describe)*

visor2 is used to aid 3D navigation for positioning of Transcranial Magnetic Stimulation (TMS) coils over preselected brain regions based on data from MRI measurements or scalp landmarks and optional EMG recording in clinical procedures. The visor2 system is compatible with the following commercially available TMS coils of the following TMS companies:

- Mag & More: PMD70-aCool Double coil Figure-8 (510575)
- MagStim Company Ltd.: Double 70mm Remote Coil (3190-00 rev2), Double 70mm Air Film Coil (3910 00);
- MagVenture A/S: Double 75mm (C-B60), Double Cooled 75mm (Cool-B65), Double 95mm (D-B80), Angulated Double Cooled 97mm (Cool-B70 rev2), Butterfly figure-8 (C-B70)
- Neuronetics Inc.: NeuroStar coil

The visor2 system must be operated by a trained physician and must not be used during surgical operations.

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

This summary is provided to support the 510(k) pre-market notification for the visor2 system.

Company Name: eemagine

Company Contact: Frank Zanow, Chief Executive Officer
eemagine Medical Imaging Solutions GmbH

Date Summary Prepared: April 8, 2022

Trade Name: visor2 system

Common Name: Accessory to Repetitive Transcranial Magnetic Stimulation

Classification Name: Repetitive Transcranial Magnetic Stimulation System
21 CFR 882.4560, Product Code: HAW, Class II

Primary Predicate: K191422, Neural Navigator
Manufacturer: Soterix Medical, Inc., New York, NY 10001

Reference Devices: K183376, HORIZON TMS Therapy System with Navigation
Manufacturer: Magstim Company Ltd., Whitland, GB Sa34 0hr

K112881, Nexstim Navigational Brain Stimulation (NBS)
System 4, Nexstim NBS System 4 with NEXSPEECH®
Manufacturer: NEXSTIM OY, Helsinki, FI Fi-00510

Date
Berlin

Reference (eemagine):
e.g. contract ID

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D-10243 Berlin
Tel. +49 30 29048404
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www.eemagine.com

CEO/Geschäftsführer:
Ralf Hauffe, Ph.D.
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BIC Code CoBaDEBB120
IBAN
DE73120400000458888500

Product Description

The visor2 system is a 3D navigation system, supporting external/surface positioning of labeling identified compatible commercially available Transcranial Magnetic Stimulation (TMS) coils based on the anatomical and functional areas for which use of the coil has been FDA cleared and as identified in cleared labeling for the coil. The visor2 system optionally records and processes electrophysiological signals to guide the user in the TMS coil placement. The visor2 system is compatible with TMS stimulators identified in the labeling that meet IEC 60601-1 and IEC 60601-1-2 electrical safety and EMC standards, a compatible optical tracking system, and further compatible accessories. Optionally, a compatible amplifier identified in the labeling may be applied for measuring electrophysiological signals. The visor2 system must be operated by a trained physician, and must not be used during surgical operations.

The visor2 system consists of a cart, an All-in-One medical computer with touch interface, a mounting plate for an optional amplifier applied for EMG recording and a Tracking camera with mounting arm. There are two fundamental visor2 system variants: single or dual display. the second configuration is available with an additional touch display added next to the All-in-One computer. Both variants are identical with regard to hardware features.

Indications for Use

visor2 is used to aid 3D navigation for positioning of Transcranial Magnetic Stimulation (TMS) coils over preselected brain regions based on data from MRI measurements or scalp landmarks and optional EMG recording in clinical procedures. The visor2 system is compatible with the following commercially available TMS coils of the following TMS companies:

- Mag & More: PMD70-aCool Double coil Figure-8 (510575)
- MagStim Company Ltd.: Double 70mm Remote Coil (3190-00 rev2), Double 70mm Air Film Coil (3910 00);
- MagVenture A/S: Double 75mm (C-B60), Double Cooled 75mm (Cool-B65), Double 95mm (D-B80), Angulated Double Cooled 97mm (Cool-B70 rev2), Butterfly figure-8 (C-B70)
- Neuronetics Inc.: NeuroStar coil

The visor2 system must be operated by a trained physician and must not be used during surgical operations.

Summary of Technological Characteristics

Substantial Equivalence Technical Characteristics					
Feature	**Subject Device visor2 system**	**Primary Predicate Neural Navigator (K191422)**	**Reference Device HORIZON TMS Therapy System with Navigation (K183376)**	**Reference Device Nexstim Navigational Brain Stimulation (NBS) System 4, Nexstim NBS System 4 with NEXSPEECH® (K112881)**	**Discussion of comparison**
Product Code, Classification	HAW (Subsequent: GWF, IKN, OBP) 21 CFR 882.4560, Class II	HAW (Subsequent: GWF, IKN, OBP) 21 CFR 882.4560, Class II	OBP, HAW, IKN 21 CFR 882.5805, Class II	GWF, HAW, IKN 21 CFR 882.1870, Class II	Classification of Subject Device, Primary Predicate and Reference Device matches. The Subject Device is an accessory to TMS therapy systems, providing location for the TMS coil.
Intended use	As an accessory to TMS systems, provide navigation, location support for placement of the TMS coil on the skull in relation to a prior acquired MRI image.	A neuronavigation system indicated for accurate positioning of the treatment coil of the CloudTMS Therapy System with respect to target brain regions based on data obtained from MRI measurements.	A repetitive transcranial magnetic stimulation system that delivers transcranial repetitive pulsed magnetic fields of sufficient magnitude to induce neural action potentials in the prefrontal cortex to treat the symptoms of major depressive	Non-invasive mapping of the primary motor cortex of the brain to its cortical gyrus. The NBS System provides information that may be used in the assessment of the primary motor cortex for pre-procedural planning.	The intended use of Subject Device, Primary Predicate and both Reference Devices match fully with regards to all aspects related to effectiveness and safety (navigation of a TMS coil relative to MRI and/or scalp landmarks/targets). As accessory to the TMS system, the device under review provides TMS coil location support. The device under review provides a locating feature to TMS systems. The device under review is an optional accessory to

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			disorder without inducing seizure.		support the intended use of TMS systems.
Indications for Use	visor2 is used to aid 3D navigation for positioning of Transcranial Magnetic Stimulation (TMS) coils over preselected brain regions based on data from MRI measurements or scalp landmarks and optional EMG recording in or clinical procedures. The visor2 system is compatible with the following commercially available TMS coils of the following TMS companies: *Mag & More:* PMD70-aCool Double coil *MagStim Company Ltd.:* Double 70mm Remote Coil (3190-00 rev2), Double 70mm Air Film (3910-00) *MagVenture A/S:* Double 75mm (C-B60), Double Cooled 75mm (Cool-B65),	The Neural Navigator is a neuronavigation system indicated for accurate positioning of the treatment coil of the CloudTMS Therapy System with respect to target brain regions based on data obtained from MRI measurements. Specifically, the Neural Navigator is indicated for use with the following CloudTMS Therapy System coils manufactured by Neurosoft Ltd: AFEC-02-100 and AFEC-02-100-C.	HORIZON® 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.	The Nexstim Navigated Brain Stimulation System (NBS System) 4 is indicated for non-invasive mapping of the primary motor cortex of the brain to its cortical gymus. The NBS System 4 provides information that may be used in the assessment of the primary motor cortex for preprocedural planning. Nexstim NEXSPEECH, when used together with the Nexstim NBS System 4, is indicated for noninvasive localization of cortical areas that do not contain essential speech function. Nexstim NEXSPEECH provides information that may be used in pre-surgical planning in patients undergoing brain surgery. Intraoperatively, the localization information provided by	The indication of use of Subject Device, Primary Predicate and both Reference Devices match fully with regard to all aspects related to effectiveness and safety (navigation of a TMS coil relative to MRI and/or scalp landmarks/targets). The Subject Device is more flexible with regard to supported coils than any of the Reference and Predicate system. As accessory to the TMS system, the device under review provides TMS coil location support. The visor2 system under review is an optional accessory to support locating/navigating TMS coil feature to existing TMS systems for their intended use. **Note:** The reference device K183376 HORIZON TMS Therapy System with Navigation includes a StimGuide feature to support TMS coil location/navigation. The StimGuide feature is a sub licensed variation of the visor2 system, was reviewed in the Horizon TMS Therapy System with Navigation, K183376, to support TMS coil location.

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	Double 95mm (D-B80), Angulated Double Cooled 97mm (Cool-B70 rev2), Butterfly figure-8 (C-B70) *Neuronetics Inc.:* NeuroStar coil The visor2 system must be operated by a trained physician and must not be used during surgical operations.			NEXSPEECH® is intended to be verified by direct cortical stimulation. The Nexstim NBS System 4 and NBS System 4 with NEXSPEECH® are not intended to be used during a surgical procedure. The Nexstim NBS System 4 and NBS System 4 with NEXSPEECH® are intended to be used by trained clinical professionals.	
TMS Coil Position Principle	Based on anatomy (MRI picture) and indirect targeting of treatment target through measured distance and direction using optical stereotactic navigation.	Based on Anatomy (MRI picture) and electro-magnetic field navigation.	Indirect targeting of treatment target through measured distance and direction using optical stereotactic navigation and anatomy.	Based on Anatomy (MRI picture) and optical stereotactic navigation.	All devices support the location/navigation of the TMS coil. The reference device K183376 HORIZON TMS Therapy System with Navigation includes a StimGuide feature to support TMS coil location/navigation uses the same methodology as the visor2 system under review. The StimGuide feature is a sub licensed variation of the visor2 system. Subject Device, Primary Predicate and both Reference Devices all use the same or equivalent position principle registering the physical head/scalp and a coil via tracker tools tracked by a stereo infrared camera 3D tracking system or in case of the Primary Predicate Device electro-magnetic field tracking. Electro-magnetic

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					field tracking and optical field tracking are both relying on identifying the position of tools in 3D space. Optical tracking is in general more precise as it relies on shorter wavelength than electrical tracking. All devices define targets either via landmarks in a co-registered MRI image (same principle in all systems using nasion-ear landmarks) or directly on the scalp. Further, all devices define a point that represents the centre position of the coil for navigation. This is either referred to as a geometrical centre of the coil defining the maximum of the field simply by geometry of the coil or referring to the electrical field maximum by design for any treatment coil including tilted designs. This point is at the geometric centre of the coil and as close as possible to the scalp surface. The display of any modelled induced electrical field in the head tissue does not impact the accuracy of the stimulus delivered relative to the target but only illustrates the field distribution of a TMS stimulus induced in head tissue. The Primary Predicate device as well as the Subject Device and the Horizon Reference device rely on geometry directly for the defining the stimulation centre point while reference K112881 calculates an E-field for this purpose. With regard to effectiveness and safety all devices follow the same working principle and perform with identical effectiveness. The Subject Device does not impose any new or additional safety risks.
Fundamental technology	Infrared locators and 3D tracking	Electro-magnetic field tracking	Infrared locators and 3D tracking	Infrared locators and camera	Comparison and discussion for this feature follows the "TMS coil

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for locating TMS coil location with regard to prior acquired MRI images	infrared camera technology for land-marking to facial and skull features using tracking tools.	using tracking tools.	infrared camera technology for land-marking to facial and skull features using tracking tools.	technology for land-marking to facial and skull feature using tracking tools. Electric field calculation used to visualize an estimated field generated by the TMS coil.	position principle". All systems/devices except Primary Predicate use the same stereo infrared 3D camera tracking principle (and same supplier for this component) to track tools attached to the TMS coil and the head in space. The predicate device uses electro-magnetic field tracking with similar accuracy. All systems except the Horizon Reference co-register an MRI image with the physical head using nasion, left and right preauricular points on the head and in the MRI image (or only on the head if individual MRI is not used). The induced electrical field of the coil is used in K112881 to represent the modelled field maximum while the Primary Predicate, the Subject Device, and the Reference device K183376 uses the coil geometry that give equivalent results. The Subject Device allows the user to optionally show the induced electrical field and align the field maximum with the targeted location. With regard to effectiveness and safety, all devices use the same principle and perform identically.
Main Components	All-In-One computer: User interface, Isolation Transformer For TMS Coil location support: 3D Tracking subsystem (Stereotactic camera positioning system), Calibration	3D Tracking subsystem Head band for TMS coil location/Navigation	HORIZON® TMS Therapy System a. HORIZON® User Interface; b. HORIZON® Mainframe; c. HORIZON® Power Supply; d. HORIZON® MT Remote Coil;	3D Tracking subsystem a. Mobile Nexstim cart b. Nexstim TMS stimulator c. Nexstim stimulation coil d. Stereotactic camera (arm-mounted tracking unit)	Both the visor2 system and primary predicate are cart based systems that substantially consist of a computer based navigation system and navigation tools and accessories. The reference device K183376 HORIZON TMS Therapy System with Navigation includes a StimGuide feature to support TMS coil location/navigation. The StimGuide feature is a sub licensed variation of the visor2 system. The same TMS coil navigation components are

Substantial Equivalence Technical Characteristics					
Feature	**<u>Subject Device</u> visor2 system**	**<u>Primary Predicate</u> Neural Navigator (K191422)**	**<u>Reference Device</u> HORIZON TMS Therapy System with Navigation (K183376)**	**<u>Reference Device</u> Nexstim Navigational Brain Stimulation (NBS) System 4, Nexstim NBS System 4 with NEXSPEECH® (K112881)**	**Discussion of comparison**
	board, Reference tracking tool, Pointer tool, Coil tracker visor2 cart eego amplifier, EE-410 (for optional EMG acquisition)		e. HORIZON® E-z Cool Coil W/StimGuide Tracking Reference ('E-z Cool Coil (SG)'); f. HORIZON® E-z Cart and Arm StimGuide Accessories: a. Interconnecting Cables; b. Footswitch; c. Pointer Tool; d. Head Reference. e. eego amplifier, EE-410 (for optional EMG acquisition)	e. 6-channel Nexstim EMG f. NBS computer system with dual 23" displays, PC and NBS software g. Three-pedal foot switch h. Nexstim cooling unit (optional) i. Electronically-adjustable patient chair j. System also includes tracking tools: NBS head tracker, coil tracker, and digitizing pen	applied in this reference device as applied in the visor2 system
Software Controlled	Yes	Yes	Yes	Yes	All devices rely on software for user interface and applicable functions. The interfaces are very similar and use workflow panels combined with 3D render views.
Software operates on a personal computer (PC)	Yes	Yes	Yes	Unknown	All devices use a very similar deployment environment on standard medical compliant computers.
Software Level of Concern	Moderate	Unknown	Moderate	Unknown	Both the vsior2 system under review and the reference device K183376 HORIZON TMS Therapy System with Navigation by the StimGuide feature have a moderate software level concern. Other devices are equivalently rated.
Prescription Only	Yes	Yes	Yes	Yes	All devices are prescription only devices for use by medical professionals.

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TMS Coil Positioning Feature	Visor2 system Applies commercially available Polaris tracking system from Northern Digital Inc.	BrainTRAK Applies electro-magnetic tracking	StimGuide feature Applies commercially available Polaris tracking system from Northern Digital Inc.	Nexstim NBS Applies commercially available Polaris tracking system from Northern Digital Inc.	All devices except Primary Predicate apply the same tracking technology. The optical and electro-magnetic tracking principle are both relying on fields that are received either by infrared sensors for optical tracking or by receiver arrays for the electro-magnetic case. These fields are analyzed via tracking tools in 3D space. Both principles are equivalent and do not differ in effectiveness or safety aspects.
TMS Coil Navigation Patient Contacting Components	Tracking Reference Pointer Tool EMG sticker Electrodes (Commercially available)	Head strap(s)	Tracking Reference Pointer Tool EMG Electrodes (Commercially available)	NBS head tracker Digitizing pen EMG Electrodes (Commercially available)	Compared to the predicate the visor2 system supports physical anatomical land marking and fixation of the Tracking reference to the head by sticker electrodes whereas the predicate applies a head strap. Using adhesive stickers in the Subject device instead of the head band can reduce risks for shifts of the tracker tool compared to the Predicate Device and will thus have the same or better effectiveness and safety.
Duration of TMS Coil tracking patient contact	< 1 hour (approximately 40 minutes in duration)	< 1 hour (approximately 40 minutes in duration)	< 1 hour (approximately 40 minutes in duration)	< 1 hour (approximately 40 minutes in duration)	The duration of the TMS procedure, including TMS coil location/navigation is less than one hour.
Tracking System Accuracy	0.25 mm RMS	1.4 mm RMS, 0.5 degrees RMS (accuracy of localization of tool)	0.25 mm RMS	1.6 mm (mean error in localization of the tool)	Compared to the predicate the visor2 system has comparable and slightly better tracking system accuracy. This is mainly attributed to the infrared optical 3D tracking principle. The tracking system accuracy of the visor2 system is the same as the StimGuide TMS coil navigation feature in the reference

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					device K183376HORIZON TMS Therapy System with navigation. All devices perform essentially identical with regard to effectiveness and safety.
System Accuracy	4 mm	3mm +/- 2.1 mm (when navigating with hand-held probe) 5mm +/- 2.1 mm (when navigating with TMS coil)	4 mm	5.73 mm (mean) 11.46 mm (95% CI)	The system accuracy is within the range of the predicate device and the reference devices. All devices perform identical with regard to effectiveness and safety.
EMG Acquisition	Yes (optional)	Yes	Yes	Yes	As an optional feature, the visor2 systems under review supports surface EMG acquisition.
Motor Threshold (MT) Response Detection	EMG provides quantitative data based on which the user defines MT.	Unknown	Option 1: EMG provides quantitative data based on which the user defines MT. Option 2: Visual qualitative monitoring for APB response.	Unknown	The visor2 system under review provides an optional EMG method for user-defined MT response detection, same as the reference device K183376 HORIZON TMS Therapy System with Navigation by the StimGuide feature. This feature is an additional indicator for the user to support anatomical navigation with functional mapping. The primary predicate does not provide this feature in their product. The additional EMG feature does not limit the effectiveness or safety of the device in any way, but supports the user with additional information on motor response due to TMS stimulation.
Scanner Interface	Import of MRI images in DICOM format. Import of fMRI/PET images. Mapping results exported as CSV text file and	DICOM import of MR images; load fMRI/PET images through import wizard. Full DICOM conformance statement available.	Unknown	DICOM import of MR images. Load fMRI/PET images through import tab. Mapping results exported as DICOM images with voxel	Compared to the predicate the import and export of files are similar and support user preferences. Supported formats are matching.

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	DICOM images with voxel coloring according to motor response amplitudes and language mapping classifications.	Mapping results exported as XML text file.		coloring according to motor response amplitudes and speech area stimulation responses.	
MRI Features: • fMRI/MRI import • MRI based head modeling • efield visualization	Yes	Yes	Yes	Yes	Same
DICOM conformance	Yes	Yes	Yes	Yes	Same
Brain segmentation	Semi-automated image segmentation of skin and brain from patient MRI.	Custom automatic tissue segmentation routine to reveal anatomical structures of the brain surface in 3D.	Unknown	Automatic tissue segmentation routine to reveal anatomical structures of the brain surface in 3D.	Segmentation is not affecting safety or effectiveness as it creates a surface for visualization of the MRI not just in slices but on curved surface in a 3D render scene. This does not change the MRI image nor positions of voxels relative to reference coordinates or landmarks. Via parameters the user can adjust the surfaces expressed by the different predicates in the word "custom" or "semi-automated".
Headmodel creation	Generation of accurate 3-D model of the patient's head.	Generation of headmodel from patient MRI.	Generation of accurate 3-D model of the patient's head.	Generation of accurate 3-D model of the patient's head.	The head model is generated in the same way as the 3D segmentation and by defining a surface of the segmented head region based in the MRI voxel space. The rendering of this does not change the MR images in any way. This feature does not affect safety nor effectiveness of the device.

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Electrical safety compliance	Yes IEC 60601-1	Yes IEC 60601-1	Yes IEC 60601-1	Yes IEC 60601-1	All devices comply with the IEC 60601-1 electrical safety requirements.
EMC compliance	Yes IEC 60601-1-2	Yes IEC 60601-1-2	Yes IEC 60601-1-2	Yes IEC 60601-1-2	All devices comply with the IEC 60601-1-2 EMC requirements.
Compatible coils	Mag & More: PMD70-aCool Double coil Figure-8; MagStim Company Ltd.: Double 70mm Remote, Double 70mm Air Film; MagVenture A/S: Double 75mm, Double Cooled 75mm, Double 95mm, Angulated Double Cooled 97mm, Butterfly figure-8; Neuronetics, Inc.: NeuroStar coil	Neurosoft Ltd: AFEC-02-100 and AFEC-02-100-C.	HORIZON: MT remote coil, E-z Cool Coil, and AFC	Nexstim: Focal Coil, High Intensity Coil, and Cooled Coil	The visor2 system under review has demonstrated compatibility with the noted commercially available TMS stimulation coils.
Operating conditions	10°C - 40°C; between 30%-70% noncondensing humidity. Air pressure 80 kPa-106 kPa	5°C - 40°C; between 10%-90% noncondensing humidity. Max allowed height for usage is 2000 m above sea level. Air pressure 79 kPa-106 kPa	Unknown	15°C- 30°C; between 30%-75% non-condensing humidity. Air Pressure 80 kPa- 106 kPa	Similar as noted. The environment of use for the visor2 system is the controlled environment of a hospital or clinic outpatient treatment room.
Electrical rating	100-240 VAC, 50/60 Hz	100-240 VAC, 50/60 Hz	Unknown	100-240 VAC, 50/60 Hz	Same as noted
Dimensions	30cm x 8cm x 8cm (approximate) (Tracking unit)	18.5 cm x 29.2 cm x 6.4 cm (Electronics Unit)	30cm x 8cm x 8cm (approximate) (Tracking unit)	27.3 cm x 6.9 cm x 6.9 cm (tracking unit)	Very similar to Predicate and not relevant to effectiveness nor safety.

Substantial Equivalence Technical Characteristics					
Feature	**Subject Device visor2 system**	**Primary Predicate Neural Navigator (K191422)**	**Reference Device HORIZON TMS Therapy System with Navigation (K183376)**	**Reference Device Nexstim Navigational Brain Stimulation (NBS) System 4, Nexstim NBS System 4 with NEXSPEECH® (K112881)**	**Discussion of comparison**
Power consumption	330 Watts	50 VA	Unknown	1000 VA	Similar as noted. The visor2 system is applied in controlled environments of a hospital or clinic outpatient treatment facility. The available power within these facilities will accommodate the power needs of the visor2.
DICOM Conformance	DICOM Conformance statement available.	DICOM conformance statement available	Unknown	DICOM Conformance statement available.	Same as noted
Planning Features	Coil targets to deliver TMS to specific area; includes visibility, location and description	Stimulation targets to deliver TMS to specific area; includes visibility, location and description	Coil targets to deliver TMS to specific area; includes visibility, location and description	Stimulation targets to deliver TMS to specific area; includes visibility, location and description of the target.	Similar as noted. The coil targets are the same as the stimulation targets.
2D and 3D viewing	Yes: axial, coronal, sagittal slices through configurable cut planes in 3D scene	Yes: axial, coronal, sagittal slices through configurable cut planes in 3D scene	Yes: axial, coronal, sagittal slices through configurable cut planes in 3D scene	Yes	Similar as noted
Scanner interface	Import of DICOM MR images, import of functional image data (fMRI), DICOM conformance statement, Mapping results exported as DICOM, text or csv files.	DICOM import of MR images; load fMRI/PET images through import wizard. Full dicom conformance statement available. Mapping results exported as XML text file.	StimGuide is not allowing DICOM or other MRI import. It only includes features for scalp based navigation.	DICOM import of MR images; load fMRI/PET images through import tab.	Similar as noted. The visor2 system can import DICOM MR images and functional image data. MR images are applied to support TMS coil positioning. PT images are not supported
Registration feature	Crosshairs to register specific MRI landmarks, pointer tool and head tracker; validation tests to	Cross-hairs to register specific MRI landmarks, digitization pen and head tracker sensors; registration integrity test to	Crosshairs to register landmarks, pointer tool and head tracker; validation tests to	Cross-hairs to register specific MRI landmarks, digitization pen and head tracker LED indicators; may perform advanced	Similar as noted. The registration feature is the same concept and method between the visor2 system and the predicate.

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	determine inaccuracies.	determine inaccuracies.	determine inaccuracies.	registration digitizing nine scalp points; registration integrity test to determine inaccuracies.	

Non-clinical Performance Tests to Demonstrate Substantial Equivalency

To establish the technical equivalency of the visor2 system, evaluations were conducted to confirm compliance with performance requirements, including:

Test	Test Method Summary	Result
Electrical Safety	IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 +A1:2012	Pass
Electromagnetic Compatibility	IEC 60601-1-2 Edition 4.0 2014-02	Pass
The visor2 system under review is an accessory to Repetitive Transcranial Magnetic Stimulation (TMS) systems.	Review and document compliance with Class II Special Controls guidance document: Repetitive Transcranial Magnetic Stimulation Systems, issued July 26, 2011	Pass
System performance to specifications	Hardware, software and system evaluations.	Pass
Biocompatibility evaluation	The Pointer Tool is the only supplied patient contacting component of the visor2 system. The patient contact materials in their final finished form, are identical to the StimGuide TMS coil location/navigation feature in K183376.	Pass
Software verification, validation	The visor2 system software was developed and documentation provided in compliance with the FDA Guidance document: Guidance for the Content of Premarket Submissions for Software Content in Medical Devices, May 11, 2005. Intentional and unintentional cybersecurity risks and mitigations are applied.	Pass

Bench testing demonstrated that the performance parameters of the visor2 system meets pre-specified requirements and are substantially equivalent to those of the predicate device. A summary of the performance testing is provided in the table below.

Test	Test Method Summary	Results
Commercial TMS Coil compatibility	Validation testing is used with users that use respective coils covering the workflow on confirming expected accuracy.	Pass The compatible commercially compatible TMS coils are

Test	Test Method Summary	Results
		demonstrated to be able to be calibrated and properly applied within the location accuracy defined by the visor2 system.
Over all accuracy of TMS coil position relative to the head (absolute value)	Worst case upper limit of the position mismatch in positioning the coil relative to the head.	Pass, Range ≤ 10 mm
Position accuracy (Tracking camera)	Volumetric Accuracy: based on a single marker stepped through more than 900 positions throughout the measurement volume using the mean of 30 samples at each position at 20°C.	Pass, Range 0.25 mm (rms) nominal
Navigation Principle	Same as the main accuracy test that covers all aspects of the main navigation principle. Further to this it is checked that the distance between target and stimulus can be reduced to 2mm. Main navigation principle is 'point based registration' between MRI space and patient space, and the calibration of navigation tools. It is tested via a comparison of known nominal positions/rotations in the physical world with tracked coil positions to covers all relevant tolerances and deviations in tools and other mechanical structures.	Main PASS criteria: The stimulus position should be within 4mm of the physical setup and the distance between stimulus target and stimulus below 2mm.
Coil Compatibility	Covered by the general test as each coil is registered by the user as part of the workflow. Coil mount fixated on the TMS coil handle. Coil tracker mount firmly attached. Coil tracker calibrated to coil dimensions via calibration board. Tracking tools material composition: Polyurethane (PUR)	Main PASS criteria: Accuracy limit in validation workflow 4mm
Coil Compatibility - Validation	The user is guided through the coil calibration and tracking steps and a questionnaire is used to trace the validation content and result. Validation reports for specific coils as listed in indications for use. Testing of coil calibration & validation in physical setup, robust with camera movement.	Passed validation
Tracking System Accuracy	Compatible camera Northern Digital Inc. (NDI) (refer to system components defined in user guide). Main relevant tests covering this aspect: In this test a coil / coil-tracking-tool is placed at known nominal positions with fully constraint orientation and measured against a ground truth in the physical scene. This covers all tolerances summing up when using the system including initial nasion-ear and coil registration steps.	Declaration of Conformity by Northern Digital Inc. and over-all system accuracy better than 4mm
System Accuracy	Same as tracking system accuracy. The tracking accuracy testing covers all tolerances summing up when using the system including initial nasion-ear and coil registration steps.	The match between positions and length in over-all system accuracy better than 4mm

Test	Test Method Summary	Results
Imaging Modality	MRI image with known landmark positions is loaded and positions of them are checked in the render 3D scene against the ground truth. MRI image with known landmark positions is loaded and positions of them are checked in the render 3D scene against the ground truth.	Main criteria: Accuracy of landmarks to MRI within 2mm.
Selection of targets via anatomical and functional landmarks	Visor2 follows the same scheme as reference HORIZON TMS Therapy System with Navigation and defines targets via anatomical or functional landmarks. The latter uses EMG. The EMG test is done by applying a known function to the input of the patient leads and making sure the waveform in visor2 follows the ground truth applied with the defined accuracy. For navigation again the overall accuracy test for the system is applied and needs to pass.	10% accuracy in EMG parameters for functional mapping Over-all position system accuracy better than 4mm

Clinical data are not needed to support substantial equivalence.

Conclusion

The visor2 system met performance requirements equivalent to the predicate device. With regard to supporting the location of the TMS coil to prior acquired MRI images, the intended use and technology of the visor2 system is the same as the predicate device.