March 17, 2023

Tonica Elektronik A/S
% Lilja Astrup
Head of RA. PM and Medical Affairs
MagVenture A/S
Lucernemarken 15
Farum, DK-3520
Denmark

Re: K221544
Trade/Device Name: MagVenture TMS Atlas Neuro Navigation System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: HAW
Dated: March 14, 2023
Received: March 14, 2023

Dear Lilja Astrup:

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

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)*
K221544

Device Name
MagVenture TMS Atlas Neuro Navigation System

Indications for Use *(Describe)*
The MagVenture TMS Atlas Neuro Navigation System is a neuronavigation system indicated for accurate positioning of the treatment coil of the MagVenture TMS Therapy system with respect to target brain regions based on data obtained from MRI measurements. Specifically, the MagVenture TMS Atlas Neuro Navigation System is indicated for use with the following MagVenture treatment coils manufactured by Tonica Elektronik A/S: C-B60, Cool-B65, Cool-B70, Cool DB80, MCF-B65, MCF-B70, and C-B70.

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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Section 5 – 510(k) Summary

5.1. Submission applicant

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5.2. Submission correspondent

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5.3. Date prepared

05/25/2022.

5.4. Device identification

Trade/Proprietary Name:	MagVenture TMS Atlas Neuro Navigation System
Common Name:	Stereotaxic Instrument
Device Classification Name:	Neurological Stereotaxic Instrument
Regulation Number:	21 CFR 882.4560
Classification Product Code:	HAW
Class:	II

Review Panel: Neurology

5.5. Legally marketed predicate device

Device Name: Neural Navigator

510(k) Number: K191422

Classification Product Code: HAW

Manufacturer: Brain Science Tools BV

5.6. Indication for use statement

The MagVenture TMS Atlas Neuro Navigation System is a neuronavigation system indicated for accurate positioning of the treatment coil of the MagVenture TMS Therapy system with respect to target brain regions based on data obtained from MRI measurements. Specifically, the MagVenture TMS Atlas Neuro Navigation System is indicated for use with the following MagVenture treatment coils manufactured by Tonica Elektronik A/S: C-B60, Cool-B65, Cool- B70, Cool D-B80, MCF-B65, MCF-B70, and C-B70.

5.7. Device description

The MagVenture TMS Atlas Neuro Navigation System (TMS Atlas system) combines MRI-based, 3-D visualization of cortical areas of the brain with non-invasive TMS in order to target brain areas accurately, and to locate the target for depression therapy. The TMS Atlas software is used to import a patient's MR image slices through standard DICOM communication protocols, and automatically generates an accurate 3-D model of the patient's head, and a custom automatic tissue segmentation routine to reveal anatomical structures of the brain surface in 3D.

5.8. Substantial equivalence discussion

The following table compares the MagVenture TMS Atlas Neuro Navigation System to the predicate device with respect to indications for use, principles of operation, technological characteristics and performance, and forms the basis for the determination of substantial equivalence.

The proposed device has the same intended use as the predicate device. The TMS Atlas system uses the same technological principle as the predicate device to accomplish its intended use,

namely the accurate positioning of a TMS coil with respect to target brain regions. The proposed device does not raise any new or different questions of safety or effectiveness as compared to the predicate device.

Comparison of technological characteristics

Attribute	MagVenture TMS Atlas Neuro Navigation System (Proposed device) [Tonica Elektronik A/S]	Neural Navigator (Predicate device) [Soterix Medical Inc.]
510(k) Number	To be assigned	K191422
Product Code	HAW	HAW
Indications For Use	The MagVenture TMS Atlas Neuro Navigation System is a neuronavigation system indicated for accurate positioning of the treatment coil of the MagVenture TMS Therapy system with respect to target brain regions based on data obtained from MRI measurements. Specifically, the MagVenture TMS Atlas Neuro Navigation System is indicated for use with the following MagVenture treatment coils manufactured by Tonica Elektronik A/S: C-B60, Cool-B65, Cool-B70, Cool D-B80, MCF-B65, MCF-B70, and C-B70.	The Neural Navigator is a neuronavigation system indicated for accurate positioning of the treatmentcoil 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.
Device description	The MagVenture TMS Atlas Neuro Navigation System (TMS Atlas system) combines MRI-based, 3-D visualization of cortical areas of the brain with non-invasive TMS in order to target brain areas accurately, and to locate the target for depression therapy. The TMS Atlas system software is used to import patient's MR image slices through standard DICOM communication protocols, and automatically generates an accurate 3-D model of the patient's head, and a custom automatic tissue segmentation routine to reveal anatomical structures of the brain surface in 3D.	The Neural Navigator combines MRI-based, 3-D localization of cortical motor areas of the brain with non-invasive TMS and simultaneous 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 Neural Navigator software is used to import a patient's MR image slices through standard DICOM communication protocols, and automatically generates an accurate 3-D model of the patient's head and a custom automatic tissue segmentation routine to reveal anatomical structures of the brain surface in 3D.
Intended users	Trained clinical professionals	Trained clinical professionals

Attribute	MagVenture TMS Atlas Neuro Navigation System (Proposed device) [Tonica Elektronik A/S]	Neural Navigator (Predicate device) [Soterix Medical Inc.]
Prescription use	Yes	Yes
Neuro navigation principle	Based on Anatomy (MRI picture) and calibrated electric field maximum	Based on Anatomy (MRI picture) and calibrated electric field maximum
Imaging modalities	MR based	MR based
MR image loading in DICOM, Nifti, and Analyze	Yes	Yes
Selection of Targets via Anatomical and Functional Landmarks	Yes	Yes
DICOM conformance	DICOM conformance statement available	DICOM conformance statement available
Planning features	Stimulation targets to deliver TMS to specific area; includes visibility, location and description of the target.	Stimulation targets to deliver TMS to specific area; includes visibility, location and description of the target.
2D 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
3D Viewing	Yes: 3D viewing of skin, brain surface and activation maps, using surface rendering techniques	Yes: 3D viewing of skin, brain surface and activation maps, using surface rendering techniques
Scanner interface	DICOM import of MR images; load fMRI/PET images through import wizard. Full DICOM conformance statement available. Mapping results exported as XML text file.	DICOM import of MR images; load fMRI/PET images through import wizard. Full DICOM conformance statement available. Mapping results exported as XML text file.
Registration features	Cross-hairs to register specific MRI landmarks, digitization pen and head tracker sensors; registration integrity test to determine inaccuracies.	Cross-hairs to register specific MRI landmarks, digitization pen and head tracker sensors; registration integrity test to determine inaccuracies.
Compatible coils	MagVenture C-B60; MagVenture Cool-B65; MagVenture Cool-B70; MagVenture Cool D-B80; MagVenture MCF-B65; MagVenture MCF-B70; MagVenture C-B70	Neurosoft AFEC-02-100-C Coil; Neurosoft AFEC-02-100 Coil

Attribute	MagVenture TMS Atlas Neuro Navigation System (Proposed device) [Tonica Elektronik A/S]	Neural Navigator (Predicate device) [Soterix Medical Inc.]
Tracking system accuracy#	1.4 mm RMS, 0.5 degrees RMS (accuracy of localization of tool)	1.4 mm RMS, 0.5 degrees RMS (accuracy of localization of tool)
System accuracy*	3mm +/- 2.1 mm (when navigating with hand-held probe), 5mm +/- 2.1 mm (when navigating with TMS coil)	3mm +/- 2.1 mm (when navigating with hand-held probe), 5mm +/- 2.1 mm (when navigating with TMS coil)
Operation conditions	5°C - 40°C; between 10%-90% non-condensing humidity. Max allowed height for usage is 2000 m above sea level. Air pressure 79 kPa-106 kPa	5°C - 40°C; between 10%-90% non-condensing humidity. Max allowed height for usage is 2000 m above sea level. Air pressure 79 kPa-106 kPa
Electrical rating	100-240 VAC, 50/60 Hz	100-240 VAC, 50/60 Hz
Dimensions (Electronics Unit)	18.5 cm x 29.2 cm x 6.4 cm	18.5 cm x 29.2 cm x 6.4 cm
Power consumption	50 VA	50 VA
Electrical safety	IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6	IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6

 # Tracking system accuracy: accuracy of the BrainTRAK position tracker
**System accuracy: accuracy of the complete TMS Atlas system*

5.9. Basis for substantial equivalence

Bench performance testing, including system and design verification and validation testing, demonstrated that the performance parameters of the proposed TMS Atlas device are substantially equivalent to those of the predicate device. A summary of the performance testing is provided in the table below.

Overview of performance testing

Test	Test method summary	Results
Navigation Principle (Based on Anatomy and calibrated EF maximum)	Main navigation principle is 'point based registration' between MRI space and patient space, and the calibration of navigation tools. It is tested via Monte Carlo simulations of the mapping algorithm and the ensuing navigation are run 10,000 times using realistic position measurement noise	Tests confirm navigation based on MRI and navigation based on EF maximum. The navigation principle of the predicate device is also based on anatomy and calibrated EF.

Test	Test method summary	Results
	conditions. The study compared the targeted site with ground-truth.	
Coil Compatibility - Validation	System validation test report to evaluate compatibility of the claimed MagVenture TMS coils and MagVenture stimulators with the TMS Atlas system as a complete system.	Testing demonstrates compatibility of the subject device to each claimed compatible TMS coil, as a complete system. It ensures that the subject device achieves the positioning accuracy that is necessary for each TMS coil to function as per their cleared Indications and Intended use. The predicate device is similarly compatible to the Neurosoft branded coils.
Tracking System Accuracy[#]	Static accuracy better than or equal to 1.4 mm as evidenced by test report provided by NDI (tracking system manufacturer) for every shipment (100% incoming inspection)	Test report confirmation. The tracking system accuracy of the predicate device is the same.
System Accuracy[*]	Monte Carlo simulations of the mapping algorithm and the ensuing navigation are run 10,000 times using realistic position measurement noise conditions.	Simulations confirm navigation accuracy of 4.55 mm with 4 markers. With 6 markers, accuracy drops to below 3.5 mm The system accuracy of the predicate device is the same.
	Compatibility testing to evaluate compatibility of the claimed MagVenture TMS coils and MagVenture stimulators with the TMS Atlas system as a complete system.	Testing demonstrates compatibility of the subject device to each claimed compatible TMS coil, as a complete system. It ensures that the subject device achieves the positioning accuracy that is necessary for each TMS coil to function as per their cleared Indications and Intended use. The achieved navigation accuracy of the system is < 4mm. The system accuracy of the predicate device is the same.
	Navigation testing that uses a phantom to evaluate whether the complete TMS Atlas system can accurately move the TMS coils to the correct location on the brain surface within claimed degree of accuracy when implemented in a real-word setting.	Testing demonstrates that the navigation algorithm can navigate accurately with an accuracy of < 5mm when implemented in a real world setting. The system accuracy of the predicate device is the same.

Test	Test method summary	Results
Product safety standards	Proposed device was tested to the following standards: IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6, IEC 80002- 1, IEC 62366, IEC 62304, ISO 14971	Compliant Test Reports. The predicate device is compliant to the same safety standards.
Imaging modality	System Testing (testing of integrated product in a setting normally encountered by the intended user)	The imaging modality is also MR based in the predicate device
Selection of targets via anatomical and functional landmarks	System Testing	The same is also used in the predicate device

 # Tracking system accuracy: accuracy of the BrainTRAK position tracker
**System accuracy: accuracy of the complete TMS Atlas system*

5.10. Labeling

The labeling of the MagVenture TMS Atlas Neuro Navigation System is substantially equivalent to that of the predicate device.

5.11. Software verification and validation

Software for the MagVenture TMS Atlas Neuro Navigation System 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, May 11, 2005;*
- *FDA guidance: General principles of software validation; Final guidance for industry and FDA staff, January 11, 2002;*
- *FDA guidance: Content of premarket submissions for management of cybersecurity in medical devices, October 18, 2018.*
- *IEC 62304:2006, Medical device software – Software life cycle processes*.

Test results indicate that the TMS Atlas system software complies with its predetermined specifications, and the standards and guidance documents.

5.11.1 System accuracy testing

Monte Carlo simulations

Verification and validation bench testing for navigation accuracy of the TMS Atlas system included Monte Carlo simulations. These simulations evaluate the accuracy of spatial alignment and the accuracy of interpolation for target locations not captured (accuracy of neuro navigation). They test the alignment algorithm in realistic conditions, and the robustness against measurement noise in the positions captured.

Monte Carlo simulations of the mapping algorithm and the ensuing navigation precision ran 10.000 times, using realistic position measurements noise conditions (as obtained from literature). The computer simulations confirm that at a realistic 3mm measurement noise level and with 4 markers, the navigation accuracy is 4.55mm mean, which is better than the 5 mm formally required.

Compatibility of TMS coils with the complete navigation system

Compatibility testing was performed to validate compatibility of the complete TMS Atlas navigation system with specific claimed TMS coils. These coils include the MagVenture coils C-B60, Cool-B65, Cool-B70, Cool D-B80, MCF-B65, MCF-B70, and C-B70. Three aspects are tested, for each coil model supported:

- absence of significant spatial distortion in position measurements
- coil calibration
- required temporal filtering during TMS discharge (a running TMS protocol)

The results indicate that all tested TMS coil and stimulator combinations, with devices powered on but not discharging, do not distort the magnetic field required for electromagnetic tracking. Coil calibration could be performed successfully for all TMS coils. All TMS coil and stimulator combinations are also compatible with the tested TMS discharge protocols, in that the spatial tracking signal distortion caused by magnetic stimuli can be effectively filtered out in real time.

As such, the compatibility testing demonstrates that the complete system achieves positioning accuracy that has been cleared for each respective TMS coil for which compatibility is claimed. It ensures that the TMS Atlas System will achieve the positioning accuracy that is necessary for each TMS coil to function as per their cleared Indications and Intended Use. The achieved navigation accuracy of the system is < 4mm.

Results of the coil calibration tests, the average of 3 tests combined and pass/fail results for each TMS coil.

TMS coil	Test 1	Test 2	Test 3	Accuracy (mean)	Result
CB60	<3mm	-	-	<3mm	PASS
CB70	2mm	-	-	2mm	PASS
CoolB65	1mm	3mm	2mm	2mm	PASS
CoolB70	3mm	-	-	3mm	PASS

CoolDB80	1mm	3mm	3mm	2mm	PASS
MCFB65	4mm	4mm	4mm	4mm	PASS
MCFB70	1mm	2mm	2mm	2mm	PASS

Navigation testing of the complete TMS Atlas system that uses a phantom

Navigation testing that uses a phantom was performed to demonstrate that the complete TMS Atlas Neuro Navigation System can accurately move the TMS coils to the correct location on the brain surface within a degree of accuracy of 5mm when implemented in a real-world setting. Testing covered all systems contributing to the navigated output, including MRI imaging and the physical movement of the TMS coil.

Sources of error were identified and included in the testing. These include sources originating from the components of the system such as the MRI scan, TMS coil, coil calibration, craniotopic markers, coil clamp and fixture, TMS discharges, and treatment chair. All measurements were taken independently of the complete system using a 'ground truth' measurement on a phantom head in order to detect the additive effects of sources of errors.

Based on the accuracy assessment that used a phantom, it is concluded that the navigation algorithm can navigate accurately when implemented in in a real world setting. All TMS coil and stimulator combinations tested are compatible with the TMS Atlas system. The complete TMS Atlas system accuracy is within the pre-defined accuracy acceptance criteria of 5 mm.

Distances from target (ground truth) to coil center in the four different tests. Results presented as mean based on 30 iterations.

	Target A (left temporal)		**Target B** (vertex)	
	Test I: Anatomical marker set (mm)	Test II: Carved "X" marker set (mm)	Test III: Anatomical marker set(mm)	Test IV: Carved "X" marker set (mm)
Mean	3.5 mm	4.6 mm	2.0 mm	2.6 mm
STDEV	0.9 mm	0.6 mm	1.2 mm	0.8 mm
Result	PASS	PASS	PASS	PASS

Navigation session with the complete TMS Atlas system

The purpose of the validation study was to show that a navigation session with the complete TMS

Atlas Neuro Navigation session achieves the navigation accuracy for TMS coil placement.

A complete navigation session is performed on a human volunteer from whom an anatomical (T1 weighted) MRI scan and a segmented gray matter map (brain) is available. Pre-defined acceptance criteria were established. Results show that the user is able to navigate the TMS coil to a defined brain target within the acceptable navigation accuracy of 5mm.

The testing concludes that the MagVenture TMS Atlas Neuro Navigation system, as a complete system, achieves the navigation accuracy for TMS coil placement when using the device as intended.

5.12. Statement of substantial equivalence

The MagVenture TMS Atlas Neuro Navigation System is substantially equivalent to the predicate device. The TMS Atlas device has the same intended use as the Neural Navigator predicate device, and the same or similar technological characteristics. Bench performance testing support the conclusion that the performance characteristics of the TMS Atlas device are substantially equivalent to the predicate device. Any differences between the devices do not raise new or different questions of safety and effectiveness.