December 22, 2021

Medtronic Navigation
Carey Brenner
Sr. Regulatory Affairs Specialist
826 Coal Creek Circle
Louisville, Colorado 80027

Re: K212397
Trade/Device Name: StealthStation S8 Cranial v2.0
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: HAW
Dated: November 3, 2021
Received: November 5, 2021

Dear Carey Brenner:

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,

Adam D. Pierce, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic 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)*
K212397

Device Name
StealthStation S8 Cranial v2.0

Indications for Use *(Describe)*

The StealthStation System, with StealthStation Cranial software, is intended as an aid for locating anatomical structures in either open or percutaneous neurosurgical procedures. Their use is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the skull, can be identified relative to images of the anatomy.

This can include, but is not limited to, the following cranial procedures (including stereotactic frame-based and stereotactic frame alternatives-based procedures):

- Tumor resections
- General ventricular catheter placement
- Pediatric ventricular catheter placement
- Depth electrode, lead, and probe placement
- Cranial biopsies

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

I. Company:

Medtronic Navigation, Inc.
826 Coal Creek Circle
Louisville, Colorado 80027 USA
Telephone Number: 720-890-3200

Contact: Carey Brenner (Primary)
Senior Regulatory Affairs Specialist
Telephone Number: 720.352.1146
Fax Number: 720.890.3500
Email: carey.j.brenner@medtronic.com

Rishi Sinha
Director Regulatory Affairs
Telephone number: 720.890.2485
Fax: 720.890.3500
Email: rishi.k.sinha@medtronic.com

II. Proprietary Trade Name: StealthStation S8 Cranial Software v2.0 Stealth Tractography

III. Classification Name: Stereotaxic Instrument (21 CFR 882.4560)

IV. Classification: Class II, Stereotaxic Instrument

V. Product Codes: HAW

VI. Predicate Device

StealthStation™ S8 Cranial Software v1.3.2, K203639
Reference Device: StealthViz™ Advanced Planning Application with StealthDTI™ Package, K081512

VII. Product Description

The StealthStation™ Cranial Software v2.0 works in conjunction with an Image Guided System (IGS) which consists of clinical software, surgical instruments, a referencing system and platform/computer hardware. Image guidance, also called navigation, tracks the position of instruments in relation to the surgical anatomy and identifies this position on diagnostic or intraoperative images of the patient. During surgery, positions of specialized surgical instruments are continuously updated on these images either by optical tracking or electromagnetic tracking.

Cranial software functionality is described in terms of its feature sets which are categorized as imaging modalities, registration, planning, interfaces with medical devices, and views. Feature sets include functionality that contributes to clinical decision making and are necessary to achieve system performance.

The changes to the currently cleared StealthStation™ S8 Cranial Software are as follows:

- Addition of white matter tractography (WMT) fiber tract creation for the brain referred to as diffusion Magnetic Resonance Imaging (dMRI) tractography. dMRI tractography will process diffusion-weighted MRI data into 3D fiber tract models that represent white-matter tracts. This will be marketed as a software option called Stealth™Tractography.

- Addition of the Medtronic SenSight™ directional DBS lead to the existing list of view overlays.
- Minor changes to the software were made to address user preferences and to fix minor anomalies.

VIII. Indications for Use

The StealthStation™ System, with StealthStation™ Cranial software, is intended as an aid for locating anatomical structures in either open or percutaneous neurosurgical procedures. Their use is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the skull, can be identified relative to images of the anatomy.

This can include, but is not limited to, the following cranial procedures (including stereotactic frame-based and stereotactic frame alternatives-based procedures):
• Tumor resections
• General ventricular catheter placement
• Pediatric ventricular catheter placement
• Depth electrode, lead, and probe placement
• Cranial biopsies

IX. Comparison of the Technological Characteristics

Attribute	**Subject Device** **Cranial Software version 2.0**	**Predicate Device** **Cranial Software (K203639)**
Intended use	The StealthStation™ System, with StealthStation™ Cranial software is designed as an aid for locating anatomical structures in either open or percutaneous neurosurgical procedures.	The StealthStation™ System, with StealthStation™ Cranial software is designed as an aid for locating anatomical structures in either open or percutaneous neurosurgical procedures.
Indications for Use	The StealthStation™ System, with StealthStation™ Cranial Software, is intended as an aid for locating anatomical structures in either open or percutaneous neurosurgical procedures. Their use is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the skull, can be identified relative to images of the anatomy. This can include, but is not limited to, the following cranial procedures (including stereotactic frame-based and stereotactic frame alternatives-based procedures): • Tumor resections • General ventricular catheter placement • Pediatric ventricular catheter placement • Depth electrode, lead, and probe placement • Cranial biopsies	The StealthStation™ System, with StealthStation™ Cranial Software, is intended as an aid for locating anatomical structures in either open or percutaneous neurosurgical procedures. Their use is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the skull, can be identified relative to images of the anatomy. This can include, but is not limited to, the following cranial procedures (including stereotactic frame-based and stereotactic frame alternatives-based procedures): • Tumor resections • General ventricular catheter placement • Pediatric ventricular catheter placement • Depth electrode, lead, and probe placement • Cranial biopsies
System Accuracy Requirement	Under representative worst-case configuration, the StealthStation™ S8 System with StealthStation™ Cranial v2.0 Software, has demonstrated performance in 3D positional accuracy with a mean error ≤ 2.0 mm and in trajectory angle accuracy with a mean error ≤ 2.0 degree.	Under representative worst-case configuration, the StealthStation™ S8 System with StealthStation™ Cranial Software, has demonstrated performance in 3D positional accuracy with a mean error ≤ 2.0 mm and in trajectory angle accuracy with a mean error ≤ 2.0

Attribute	Subject Device Cranial Software version 2.0	Predicate Device Cranial Software (K203639)
Imaging Modalities	X-Ray based, MR based, Nuclear Medicine based	X-Ray based, MR based, Nuclear Medicine based
View (Display) Features	Ultrasound Video In, Ultrasound Overlay, 3D, 2D Anatomic Orthogonal, Trajectory 1 and 2, Target Guidance, Trajectory Guidance, Probes Eye, Look Ahead, Microscope Injection, Video Input, Endoscopic	Ultrasound Video In, Ultrasound Overlay, 3D, 2D Anatomic Orthogonal, Trajectory 1 and 2, Target Guidance, Trajectory Guidance, Probes Eye, Look Ahead, Microscope Injection, Video Input, Endoscopic
Exam-to-Exam Registration Features	Identity Merge Registration, Manual Merge Registration and Automatic Merge Registration	Identity Merge Registration, Manual Merge Registration and Automatic Merge Registration
Patient Registration Features	PointMerge™ registration (referred to as Landmark registrations), Tracer™ registration, Touch registration (previously Touch-N-Go™), StealthAiR™ registration, O-arm™ registration, Mechanical based registrations (Stereotactic Localizer Registration and StarFix™ Bone Anchor Registation)	PointMerge™ registration (referred to as Landmark registrations), Tracer™ registration, Touch registration (previously Touch-N-Go™), StealthAiR™ registration, O-arm™ registration, Mechanical based registrations (Stereotactic Localizer Registration and StarFix™ Bone Anchor Registration)
Planning Features	3D Model Building, including fiber tracts with Standard DTI and Enhanced CSD techniques Plan Entry and Target Selection Advanced Visualization Create Patient Based Anatomical Coordinate Space Stereotactic Frame Settings Brain Atlas: Schaltenbrand- Wahren Atlas with Talairach Grid STarFix™ Designer Annotations	3D Model Building (which includes DTI fiber tracts imported from StealthViz) Plan Entry and Target Selection Advanced Visualization Create Patient Based Anatomical Coordinate Space Stereotactic Frame Settings Brain Atlas: Schaltenbrand- Wahren Atlas with Talairach Grid STarFix™ Designer Annotations
Medical Device Interfaces	Microscope Navigation: Zeiss, Leica Ultrasound Navigation: Aloka and Sonosite Medtronic O-arm® Stereotactic Frame Systems: Fischer ZD, Fischer RM, Integra CRW and Elekta Leksell Nexframe® Stereotactic System STarFix™Platform System	Microscope Navigation: Zeiss, Leica Ultrasound Navigation: Aloka and Sonosite Medtronic O-arm® Stereotactic Frame Systems: Fischer ZD, Fischer RM, Integra CRW and Elekta Leksell Nexframe® Stereotactic System STarFix™Platform System
Compatible Medtronic Optical Instrumentation	Medtronic instruments tracked via optical markers or LEDs located on instrument and patient trackers via the optical localizing system.	Medtronic instruments tracked via optical markers or LEDs located on instrument and patient trackers via the optical localizing system.

Attribute	Subject Device Cranial Software with dMRI Tractography	Predicate Device Cranial Software (K203639)
Compatible Medtronic EM Instrumentation	Medtronic instruments tracked via Electromagnetic localization technology located within the instrument and patient trackers	Medtronic instruments tracked via Electromagnetic localization technology located within the instrument and patient trackers
Software Interface (GUI)	Black and gray style with procedure task overview in left menu option and next/back task flow at bottom of the screen. Software controls for images, planning and instrument management and tractography editing are contained in a right side bar.	Black and gray style with procedure task overview in left menu option and next/back task flow at bottom of the screen. Software controls for images, planning and instrument management are contained in a right side bar.
Programming Language	C++/Java	C++
Scanner Interface Technology (to imaging devices)	Network Connectivity CD, DVD, USB DICOM Import DICOM Export	Network Connectivity CD, DVD, USB DICOM Import DICOM Export
Optical Technology	Manufacturer: (Northern Digital Inc.) Localizer: Vega	Manufacturer: (Northern Digital Inc.) Localizer: Vega
Electromagnetic Technology	Manufacturer: (Medtronic Navigation, Inc.) Localizer: AxiEM III Emitter Types: Side, Flat	Manufacturer: (Medtronic Navigation, Inc.) Localizer: AxiEM III Emitter Types: Side, Flat

X. Discussion of the Performance Testing

The following table summarizes the testing conducted on the StealthStation™ Cranial Software v2.0

Description
Under representative worst-case configuration, the StealthStation™ S8 System with StealthStation™ Cranial Software v2.0 has demonstrated performance in 3D positional accuracy with a mean error ≤ 2.0 mm and in trajectory angle accuracy with a mean error of ≤ 2.0 degrees. This performance was determined using anatomically representative phantoms and utilizing a subset of system components and features that represent the worst-case combinations of all potential system components.
Software verification and validation testing verified the software requirements are met and the software performs as intended.
Summative usability validation and clinical expert evaluation were performed by representative users on datasets not used for development, composed of normal and abnormal brains in both pediatric and adult populations. Summative evaluations demonstrated StealthStation™ Cranial Software v2.0 with Stealth™ Tractography has been found to be safe and effective for the intended users, uses and use environments. Performance testing demonstrated the design and implementation of the correct creation and rendering of dMRI tracts in views in the application and the functionality of the dMRI tractography feature requirements. Clinical expert evaluations included white matter tract generation and editing which are new in the StealthStation™ S8 software. Clinical experts assessed the rendering of the white matter tracts and their relationship to other key structures with respect to treatment planning, intraoperative navigation and the potential to aid clinical decision making.

The following table summarizes the quality assurance measures that were applied during development of the software component of the system:

Description
Software Development Life Cycle
Software Risk Assessment
Software Configuration Management and Version Control

XII. Conclusions

The StealthStation™ Cranial Software v2.0 has been found through performance testing and comparison to be substantially equivalent to the identified predicate device. Performance testing in combination with the clinical expert evaluation demonstrates the StealthStation™ Cranial v2.0 software performs as intended and demonstrates substantial equivalence to the predicate device.