October 19, 2023

Medtronic Navigation, Inc.
Rishi Mehta
Senior Regulatory Affairs Specialist
200 Medtronic Drive
Lafayette, Colorado 80026

Re: K231976
Trade/Device Name: StealthStation Cranial Software, v3.1.5 (9735585)
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: HAW
Dated: September 19, 2023
Received: September 19, 2023

Dear Rishi Mehta:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 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 systems (QS) regulation (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.

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,

Adam D. Pierce -S

Digitally signed by Adam D. Pierce -S
Date: 2023.10.19 11:31:58 -04'00'

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

K231976

Device Name
StealthStation Cranial Software Version 3.1.5 (9735585)

Indications for Use *(Describe)*

StealthStation Cranial Software Version 3.1.5

The StealthStation System, with StealthStation Cranial software, is intended to aid in precisely locating anatomical structures in either open or percutaneous neurosurgical procedures. The system is indicated for any medical condition in which reference to a rigid anatomical structure 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):

- Cranial biopsies (including stereotactic)
- Deep brain stimulation (DBS) lead placement
- Depth electrode placement
- Tumor resections
- Craniotomies/Craniectomies
- Skull Base Procedures
- Transsphenoidal Procedures
- Thalamotomies/Pallidotomies
- Pituitary Tumor Removal
- CSF leak repair
- Pediatric Ventricular Catheter Placement
- General Ventricular Catheter Placement

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

October 19, 2023

I. Company:

Medtronic Navigation, Inc.
200 Medtronic Drive
Lafayette, CO, 80026
Telephone Number: 720-890-2462
Fax Number: 720-890-3500

Contact: Rishi Mehta
Senior Regulatory Affairs Specialist
Telephone Number: 720-890-2462

Kyle Hoefling
Senior Regulatory Affairs Manager
Telephone Number: 720-890-2462

II. Proprietary Trade Name: StealthStation™ Cranial Software v3.1.5

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

IV. Classification: Class II, Stereotaxic Instrument

V. Product Codes: HAW

VI. Predicate: Medtronic Navigation, Inc. manufactured software;

- K221087 StealthStation Cranial Software v3.1.4

VII. Product Description

The StealthStation System, with StealthStation Cranial software helps guide surgeons during cranial surgical procedures such as biopsies, tumor resections, and shunt and lead placements. The StealthStation Cranial Software 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. StealthStation 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.

VIII. Indications for Use

StealthStation Cranial Software Version 3.1.5

The StealthStation System, with StealthStation Cranial Software, is intended to aid in precisely locating anatomical structures in either open or percutaneous neurosurgical procedures. The system is indicated for any medical condition in which reference to a rigid anatomical structure 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):

- Cranial biopsies (including stereotactic)
- Deep brain stimulation (DBS) lead placement
- Depth electrode placement
- Tumor resections
- Craniotomies/Craniectomies
- Skull Base Procedures
- Transsphenoidal Procedures
- Thalamotomies/Pallidotomies
- Pituitary Tumor Removal
- CSF leak repair
- Pediatric Ventricular Catheter Placement
- General Ventricular Catheter Placement

IX. Summary of the Technological Characteristics

StealthStation Cranial Software Version 3.1.5 as compared to Predicate Device

Item	**Subject Device** StealthStation System with Cranial Software Version 3.1.5	**Predicate Device** StealthStation System with StealthStation Cranial Software Version 3.1.4 (K221087)
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 to aid in locating anatomical structures in either open or percutaneous neurosurgical procedures. The system is indicated for any medical condition in which reference to a rigid anatomical	The StealthStation System, with StealthStation Cranial software, is intended to aid in locating anatomical structures in either open or percutaneous neurosurgical procedures. The system is indicated for any medical condition in which reference to a rigid anatomical

Item	Subject Device StealthStation System with Cranial Software Version 3.1.5	Predicate Device StealthStation System with StealthStation Cranial Software Version 3.1.4 (K221087)
	structure 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): - Cranial Biopsies - Deep brain stimulation (DBS) lead placement - Depth electrode placement - Tumor Resections - Craniotomies/Craniectomies - Skull Base Procedures - Transsphenoidal Procedures - Thalamotomies/Pallidotomies - Pituitary Tumor Removal - CSF Leak Repair - Pediatric Ventricular Catheter Placement - General Ventricular Catheter Placement The user should consult the "Navigational Accuracy" section of the User Manual to assess if the accuracy of the system is suitable to their needs.	structure 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): - Cranial Biopsies - Deep brain stimulation (DBS) lead placement - Depth electrode placement - Tumor Resections - Craniotomies/Craniectomies - Skull Base Procedures - Transsphenoidal Procedures - Thalamotomies/Pallidotomies - Pituitary Tumor Removal - CSF Leak Repair - Pediatric Ventricular Catheter Placement - General Ventricular Catheter Placement The user should consult the "Navigational Accuracy" section of the User Manual to assess if the accuracy of the system is suitable to their needs.
System Accuracy Requirement	Under representative worst-case configuration, the StealthStation® 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 degrees. <u>Specific Mean Accuracy Values</u> Positional Error - 0.824 mm Trajectory Error - 0.615 degrees	Under representative worst-case configuration, the StealthStation® 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 degrees. <u>Specific Mean Accuracy Values</u> Positional Error - 1.27 mm Trajectory Error – 1.02 degrees

Item	Subject Device StealthStation System with Cranial Software Version 3.1.5	Predicate Device StealthStation System with StealthStation Cranial Software Version 3.1.4 (K221087)
Imaging Modalities	X-Ray based, MR based Nuclear Medicine based	X-Ray based, MR based Nuclear Medicine based
Registration Features	Exam-to-Exam Registration: Identity Merge Registration, Manual Merge Registration and Automatic Merge Registration. Patient Registration: PointMerge registration, Tracer registration, Touch-N-Go registration, StealthAiR registration, O-arm registration, Stereotactic Localizer Registration and StarFix Bone Anchor Registration	Exam-to-Exam Registration: Identity Merge Registration, Manual Merge Registration and Automatic Merge Registration. Patient Registration: PointMerge registration, Tracer registration, Touch-N-Go registration, StealthAiR registration, O-arm registration, Stereotactic Localizer Registration and StarFix Bone Anchor Registration
Planning Features	Plan Entry and Target Selection 3D Model Building Advanced Visualization Create Patient Based Anatomical Coordinate Space Stereotactic Frame Settings Brain Atlas: Schaltenbrand-Wahren Atlas with Talairach Grid STarFix Designer Annotations	Plan Entry and Target Selection 3D Model Building 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 Leksell Nexframe® Stereotactic System STarFix™Platform	Microscope Navigation: Zeiss, Leica Ultrasound Navigation: Aloka and Sonosite Medtronic O-arm Stereotactic Frame Systems: Fischer ZD, Fischer RM, Integra CRW and Leksell Nexframe® Stereotactic System STarFix™Platform
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	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
Software Interface (GUI)	Blue style with chronological next/back task flow at the top of the screen. Image controls on the left. Planning information on the right.	Blue style with chronological next/back task flow at the top of the screen. Image controls on the left. Planning information on the right.

Item	Subject Device StealthStation System with Cranial Software Version 3.1.5	Predicate Device StealthStation System with StealthStation Cranial Software Version 3.1.4 (K221087)
Programming Language	C++	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
Localization Technology	Optical (infra-red) Electromagnetic Mechanical based stereotactic	Optical (infra-red) Electromagnetic Mechanical based stereotactic

X. Identification of Legally Marketing Devices

- K190672, StealthStation Cranial Software v3.1.1
- K221087, StealthStation Cranial Software v3.1.4

XI. Discussion of the Performance Testing

Testing conducted demonstrates the product will perform as intended according to the outlined design requirements. The following testing was conducted on the StealthStation Cranial Software to establish substantial equivalence of the system and verify that the device will perform as intended meeting all of the design inputs:

- Verification corrective testing to verify the software changes addressed the Biopsy Depth Gauge Graphic and the Distance to/past Target Text anomalies.
- Verification regression testing to confirm that changes introduced to the software do not adversely affect the functionality of the software.
- Verify the new software version will install and upgrade properly.
- Verify the changes to the instructions for use (IFU).
- User exploratory testing to explore clinical workflows, including standard and unusual clinically relevant workflows. This testing will include subject matter experts, internal and field support personnel.
- System accuracy validation testing to demonstrate that the modified software meets the accuracy acceptance criteria of ≤2.0mm and ≤2.0 degrees, established in previous 510(k) submissions for the predicate device, the StealthStation S7 System.

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 has been shown through testing and comparison to be substantially equivalent to the identified predicate device.