June 10, 2022

Medtronic Navigation, Inc.
Silver Wirth
Regulatory Affairs Specialist
826 Coal Creek Circle
Louisville, Colorado 80027

Re: K221087
Trade/Device Name: Synergy Cranial v2.2.9, StealthStation Cranial v3.1.4
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: HAW
Dated: April 11, 2022
Received: April 13, 2022

Dear Silver Wirth:

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)*
K221087

Device Name
Synergy Cranial v2.2.9 (9733763);
StealthStation Cranial v3.1.4 (9735585)

Indications for Use *(Describe)*

Synergy Cranial v2.2.9:
The StealthStation System, with Synergy Cranial software, is intended as an aid for 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:

- Cranial Biopsies
- Tumor Resections
- Craniotomies/Craniectomies
- Skull Base Procedures
- Transsphenoidal Procedures
- Thalamotomies/Pallidotomies
- Pituitary Tumor Removal
- CSF Leak Repair
- Pediatric Catheter Shunt Placement
- General Catheter Shunt Placement

StealthStation Cranial Software v3.1.4:
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

April 11, 2022

I. Company: Medtronic Navigation, Inc.
826 Coal Creek Circle
Louisville, Colorado 80027 USA
Telephone Number: 720-890-3200
Fax Number: 720-890-3500

Contact: Silver Wirth
Regulatory Affairs Specialist
Telephone Number: 720-890-3200

Olga Lewis (Alternate)
Senior Regulatory Affairs Manager
Telephone Number: 720-890-3200

II. Proprietary Trade Name: StealthStation™ Cranial Software

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

IV. Classification: Class II, Stereotaxic Instrument

V. Product Codes: HAW

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

- K190672, StealthStation Synergy Cranial S7 Software v2.2.8, StealthStation Cranial Software v3.1.1

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

<u>Cranial Software v2.2.9</u>

The StealthStation System, with Synergy Cranial software, is intended as an aid for 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:
- Cranial Biopsies
- Tumor Resections
- Craniotomies/Craniectomies
- Skull Base Procedures
- Transsphenoidal Procedures
- Thalamotomies/Pallidotomies
- Pituitary Tumor Removal
- CSF Leak Repair
- Pediatric Catheter Shunt Placement
- General Catheter Shunt Placement

Cranial Software v3.1.3
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 v2.2.9 as compared to Predicate Device

Item	**Subject Device** StealthStation System with Synergy Cranial v2.2.9 Software	**Predicate Device** K190672 StealthStation System with Synergy Cranial v2.2.8 Software
Intended Use	The StealthStation System, with Synergy Cranial software is designed as an aid for	The StealthStation System, with Synergy Cranial software is designed as an aid for

Item	**Subject Device** StealthStation System with Synergy Cranial v2.2.9 Software	**Predicate Device** K190672 StealthStation System with Synergy Cranial v2.2.8 Software
	precisely locating anatomical structures in either open or percutaneous neurosurgical procedures.	precisely locating anatomical structures in either open or percutaneous neurosurgical procedures.
Indications for Use	The StealthStation System, with Synergy Cranial software, is intended as an aid for 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: - Cranial Biopsies - Tumor Resections - Craniotomies/Craniectomies - Skull Base Procedures - Transsphenoidal Procedures - Thalamotomies/Pallidotomies - Pituitary Tumor Removal - CSF Leak Repair - Pediatric Catheter Shunt Placement - General Catheter Shunt Placement	The StealthStation System, with Synergy Cranial software, is intended as an aid for 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: - Cranial Biopsies - Tumor Resections - Craniotomies/Craniectomies - Skull Base Procedures - Transsphenoidal Procedures - Thalamotomies/Pallidotomies - Pituitary Tumor Removal - CSF Leak Repair - Pediatric Catheter Shunt Placement - General Catheter Shunt Placement
System Accuracy Requirement	Under representative worst-case configuration, the StealthStation® System with Synergy 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> Position Error - 1.29 mm Trajectory Error - 0.87 degrees	Under representative worst-case configuration, the StealthStation® System with Synergy® 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 – 0.70 mm Trajectory Error – 0.46 degrees
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.	Exam-to-Exam Registration: Identity Merge Registration, Manual Merge Registration and Automatic Merge Registration.

Item	Subject Device StealthStation System with Synergy Cranial v2.2.9 Software	Predicate Device K190672 StealthStation System with Synergy Cranial v2.2.8 Software
	Patient Registration: PointMerge registration, Tracer registration, Touch-N-Go registration, StealthAiR registration and O-arm registration	Patient Registration: PointMerge registration, Tracer registration, Touch-N-Go registration, StealthAiR registration and O-arm registration
Planning Features	Plan Entry and Target Selection 3D Model Building Advanced Visualization	Plan Entry and Target Selection 3D Model Building Advanced Visualization
Medical Device Interfaces	Microscope Navigation: Zeiss, Leica Ultrasound Navigation: Aloka and Sonosite Medtronic O-arm	Microscope Navigation: Zeiss, Leica Ultrasound Navigation: Aloka and Sonosite Medtronic O-arm
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.
Programming Language	C++	C++
Scanner Interface Technology (to imaging devices)	Network Connectivity CD, DVD, USB DICOM or Stealth format Import Export in Stealth format	Network Connectivity CD, DVD, USB DICOM or Stealth format Import Export in Stealth format
Localization Technology	Optical (infra-red) Electromagnetic	Optical (infra-red) Electromagnetic

StealthStation Cranial Software v3.1.3 as compared to Predicate Device

Item	Subject Device StealthStation System with Cranial v3.1.3 Software	Predicate Device K190672 StealthStation System with StealthStation Cranial v3.1.1 Software
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 v3.1.3 Software	**Predicate Device** K190672 StealthStation System with StealthStation Cranial v3.1.1 Software
	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 v3.0 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 degrees. <u>Specific Mean Accuracy Values</u> Position Error - 1.27 mm Trajectory Error - 1.02 degrees	Under representative worst-case configuration, the StealthStation® System with StealthStation® Cranial v3.0 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 degrees. <u>Specific Mean Accuracy Values</u> Positional Error – 1.16 mm Trajectory Error – 0.41 degrees
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.	Exam-to-Exam Registration: Identity Merge Registration, Manual Merge Registration and Automatic Merge Registration.

Item	**Subject Device** StealthStation System with Cranial v3.1.3 Software	**Predicate Device** K190672 StealthStation System with StealthStation Cranial v3.1.1 Software
	Patient Registration: PointMerge registration, Tracer registration, Touch-N-Go registration, StealthAiR registration, O-arm registration, Stereotactic Localizer Registration and StarFix Bone Anchor 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.
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 Synergy Cranial S7 Software v2.2.8, StealthStation Cranial Software v3.1.1

XI. Discussion of the Performance Testing

The following table summarizes the testing conducted on the StealthStation System with StealthStation Cranial Software:

Description
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. 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. The test configurations included CT images with slice spacing and thickness ranging between 0.6 mm to 1.25 mm and T1-weighted MR images with slice spacing and thickness ranging between 1.0 mm to 3.0 mm. In the imaging protocol, we recommend slice spacing and thickness for CT and MR imaging to be 1.0 mm or less.
Software verification and validation testing for each requirement specification. Design verification and validation was performed using the StealthStation Cranial software in laboratory and simulated use settings. The results support the safety of the device and demonstrate that the software should perform as intended in the specified use conditions.
System integration performance testing for cranial surgical procedures using anatomical phantoms.

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 devices.