June 3, 2020

Medtronic Navigation Inc.
Amelia Striegel
Senior Regulatory Affairs Specialist
826 Coal Creek Circle
Louisville, Colorado 80027

Re: K201175
Trade/Device Name: StealthStation Cranial Software v1.3.0
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: HAW
Dated: April 30, 2020
Received: May 1, 2020

Dear Amelia Striegel:

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
Acting 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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*

K201175

Device Name
StealthStation™ Cranial Software v1.3.0

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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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**510(k) Summary**

30 April 2020

**I. Company:**

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

**Contact:**

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Fax Number: 720.890.3500

K. Elizabeth Waite
Regulatory Affairs Manager
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Email: elizabeth.waite@medtronic.com

**II. Proprietary Trade Name:** StealthStation™ Cranial Software v1.3.0

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

**IV. Classification:** Class II, Stereotaxic Instrument

**V. Product Codes:** HAW

**VI. Predicate Device**

510(k): K162309
Device name: StealthStation S8 Cranial Software v1.0.0
Manufacturer: Medtronic Navigation, Inc.

**VII. Product Description**

The StealthStation™ Cranial Software v1.3.0 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 an optional image display that allows the user to see through outer layers to increase the visibility of other models.

- Update the imaging protocol to support overlapping slices.
- 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

| Feature | StealthStation Cranial Software v1.3.0 (Subject Device) | StealthStation S8 Cranial software v1.0.0 (Predicate Device; K162309) |
|---|---|---|
| **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. |

| Feature | StealthStation Cranial Software v1.3.0 (Subject Device) | StealthStation S8 Cranial software v1.0.0 (Predicate Device; K162309) |
|---|---|---|
| **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.<br><br>This can include, but is not limited to, the following cranial procedures (including stereotactic frame-based and stereotactic frame alternatives-based procedures):<br>• Tumor resections<br>• General ventricular catheter placement<br>• Pediatric ventricular catheter placement<br>• Depth electrode, lead, and probe placement<br>• 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.<br><br>This can include, but is not limited to, the following cranial procedures (including stereotactic frame-based and stereotactic frame alternatives-based procedures):<br>• Tumor resections<br>• General ventricular catheter placement<br>• Pediatric ventricular catheter placement<br>• Depth electrode, lead, and probe placement<br>• Cranial biopsies |
| **System Accuracy Requirements** | Under representative worst-case configuration, the StealthStation S8 System with StealthStation Cranial Software v1.3.0, 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. | Under representative worst-case configuration, the StealthStation S8 System with StealthStation Cranial v1.0.0 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. |
| **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 |

| Feature | StealthStation Cranial Software v1.3.0 (Subject Device) | StealthStation S8 Cranial software v1.0.0 (Predicate Device; K162309) |
|---|---|---|
| **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 Registration) | 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** | Plan Entry and Target Selection<br>3D Model Building<br>Advanced Visualization<br>Create Patient Based Anatomical Coordinate Space<br>Stereotactic Frame Settings<br>Brain Atlas: Schaltenbrand-Wahren Atlas with Talairach Grid<br>STarFix™ Designer Annotations | Plan Entry and Target Selection<br>3D Model Building<br>Advanced Visualization<br>Create Patient Based Anatomical Coordinate Space<br>Stereotactic Frame Settings<br>Brain Atlas: Schaltenbrand-Wahren Atlas with Talairach Grid<br>STarFix™ Designer Annotations |
| **Medical Device Interfaces** | Microscope Navigation: Zeiss, Leica<br>Ultrasound Navigation: Aloka and Sonosite<br>Medtronic O-arm™<br>Stereotactic Frame Systems: Fischer ZD, Fischer RM, Integra CRW and Elekta Leksell<br>Nexframe™ Stereotactic System<br>STarFix™Platform System<br>Stealth Midas Rex MR8<br>StealthStation Autoguide | Microscope Navigation: Zeiss, Leica<br>Ultrasound Navigation: Aloka and Sonosite<br>Medtronic O-arm®<br>Stereotactic Frame Systems: Fischer ZD, Fischer RM, Integra CRW and Elekta Leksell<br>Nexframe® Stereotactic System<br>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. |
| **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 |

| Feature | StealthStation Cranial Software v1.3.0 (Subject Device) | StealthStation S8 Cranial software v1.0.0 (Predicate Device; K162309) |
|---|---|---|
| **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 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++ | C++ |
| **Scanner Interface Technology (to imaging devices)** | Network Connectivity<br>CD, DVD, USB<br>DICOM Import<br>DICOM Export | Network Connectivity<br>CD, DVD, USB<br>DICOM Import<br>DICOM Export |
| **Optical Technology** | Manufacturer: Northern Digital Inc.<br>Localizer: Vega | Manufacturer: Northern Digital Inc.<br>Localizer: Vega |
| **Electromagnetic Technology** | Manufacturer: Medtronic Navigation, Inc.<br>Localizer: AxiEM III<br>Emitter Types: Side, Flat | Manufacturer: Medtronic Navigation, Inc.<br>Localizer: AxiEM III<br>Emitter Types: Side, Flat |

## X. Identification of Legally Marketed Devices

StealthStation S8 Cranial Software v1.0.0 (K162309)

## XI. Discussion of the Performance Testing

The following table summarizes the testing conducted on the StealthStation Cranial Software v1.3.0

| Description |
|---|
| Under representative worst-case configuration, the StealthStation S8 System with StealthStation Cranial Software v1.3.0 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 for each requirement specification. |
| 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 |

Design verification and validation was performed using the StealthStation S8 System with StealthStation Cranial Software v1.3.0 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.

Clinical testing was not considered necessary prior to release as this is not new technology.

## XII. Conclusions

The StealthStation Cranial Software v1.3.0 has been shown through testing and comparison to be substantially equivalent to the identified predicate device.