July 31, 2019

Medtronic Navigation Inc.
Elizabeth Waite
Principal Regulatory Affairs Specialist
826 Coal Creek Circle
Louisville, Colorado 80027

Re: K190672

Trade/Device Name: StealthStation Synergy Cranial S7 Software v.2.2.8, StealthStation Cranial Software v3.1.1
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: HAW
Dated: March 14, 2019
Received: March 15, 2019

Dear Elizabeth Waite:

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...
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.


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,

Michael J. Hoffmann -S

for Matthew Krueger
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
Indications for Use

The Synergy® Cranial software is surgical navigation software that, when used with the StealthStation® System as a planning and intraoperative guidance system, 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:

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

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

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASTaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."
Indications for Use

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/Craniecotomies
- 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.

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

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."
510(k) Summary

April 18, 2019

   826 Coal Creek Circle
   Louisville, Colorado 80027 USA
   Telephone Number: 720-890-3200
   Fax Number: 720-890-3500

Contact: K. Elizabeth Waite (Primary)
   Principal Regulatory Affairs Specialist
   Telephone Number: 720-890-2182
   Fax Number: 720-890-3500

Rishi Sinha (Alternate)
   Regulatory Affairs Manager
   Telephone Number: 720-890-2485
   Fax Number: 720-890-3500

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;
   • K150216, StealthStation System with Synergy Cranial v2.2.7 software
   • K153660, StealthStation System with StealthStation Cranial v3.0 Software

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

Cranial Software v2.2.8
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 v3.1.1
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
IX. Summary of the Technological Characteristics

StealthStation Cranial Software v2.2.8 as compared to Predicate Device

<table>
<thead>
<tr>
<th>Item</th>
<th>Subject Device</th>
<th>Predicate Device</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Intended Use</strong></td>
<td>The StealthStation® System, with Synergy® Cranial software is designed as an aid for precisely locating anatomical structures in either open or percutaneous neurosurgical procedures.</td>
<td>The StealthStation® System, with Synergy® Cranial software is designed as an aid for precisely locating anatomical structures in either open or percutaneous neurosurgical procedures.</td>
</tr>
<tr>
<td><strong>Indications for Use</strong></td>
<td>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.</td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td>This can include, but is not limited to, the following cranial procedures:</td>
<td>This can include, but is not limited to, the following cranial procedures:</td>
</tr>
<tr>
<td></td>
<td>- Cranial Biopsies</td>
<td>- Cranial Biopsies</td>
</tr>
<tr>
<td></td>
<td>- Tumor Resections</td>
<td>- Tumor Resections</td>
</tr>
<tr>
<td></td>
<td>- Craniotomies/Craniectomies</td>
<td>- Craniotomies/Craniectomies</td>
</tr>
<tr>
<td></td>
<td>- Skull Base Procedures</td>
<td>- Skull Base Procedures</td>
</tr>
<tr>
<td></td>
<td>- Transsphenoidal Procedures</td>
<td>- Transsphenoidal Procedures</td>
</tr>
<tr>
<td></td>
<td>- Thalamotomies/Pallidotomies</td>
<td>- Thalamotomies/Pallidotomies</td>
</tr>
<tr>
<td></td>
<td>- Pituitary Tumor Removal</td>
<td>- Pituitary Tumor Removal</td>
</tr>
<tr>
<td></td>
<td>- CSF Leak Repair</td>
<td>- CSF Leak Repair</td>
</tr>
<tr>
<td></td>
<td>- Pediatric Catheter Shunt Placement</td>
<td>- Pediatric Catheter Shunt Placement</td>
</tr>
<tr>
<td></td>
<td>- General Catheter Shunt Placement</td>
<td>- General Catheter Shunt Placement</td>
</tr>
<tr>
<td><strong>System Accuracy</strong></td>
<td>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.</td>
<td>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.</td>
</tr>
<tr>
<td><strong>Requirement</strong></td>
<td><strong>Specific Mean Accuracy Values</strong></td>
<td><strong>Specific Mean Accuracy Values</strong></td>
</tr>
<tr>
<td></td>
<td>Positional Error – 0.70 mm</td>
<td>Positional Error - ≤ 2.00 mm</td>
</tr>
</tbody>
</table>
### StealthStation Cranial Software v3.1.1 as compared to Predicate Device

<table>
<thead>
<tr>
<th>Item</th>
<th>Subject Device</th>
<th>Predicate Device</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>StealthStation Cranial Software v3.1.1 as compared to Predicate Device</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Item</strong></td>
<td><strong>Subject Device</strong></td>
<td><strong>Predicate Device</strong></td>
</tr>
<tr>
<td></td>
<td>StealthStation System with Cranial v3.1.1 Software</td>
<td>K153660 StealthStation System with StealthStation Cranial v3.0 Software</td>
</tr>
<tr>
<td>Intended Use</td>
<td>The StealthStation® System, with StealthStation® Cranial software is designed as</td>
<td>The StealthStation® System, with StealthStation® Cranial software is designed as</td>
</tr>
<tr>
<td></td>
<td>an aid for locating anatomical structures in either open or percutaneous</td>
<td>an aid for locating anatomical structures in either open or percutaneous</td>
</tr>
<tr>
<td></td>
<td>neurosurgical procedures.</td>
<td>neurosurgical procedures.</td>
</tr>
</tbody>
</table>

### Additional Information

<table>
<thead>
<tr>
<th>Item</th>
<th>Subject Device</th>
<th>Predicate Device</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Item</strong></td>
<td><strong>Subject Device</strong></td>
<td><strong>Predicate Device</strong></td>
</tr>
<tr>
<td><strong>Subject Device</strong></td>
<td>StealthStation System with Synergy Cranial v2.2.8 Software</td>
<td>K150216 StealthStation System with Synergy Cranial v2.2.7 Software</td>
</tr>
<tr>
<td><strong>Predicate Device</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trajectory Error – 0.46 degrees</td>
<td>Trajectory Error - ≤ 2.0°</td>
<td></td>
</tr>
<tr>
<td>Imaging Modalities</td>
<td>X-Ray based, MR based, Nuclear Medicine based</td>
<td>X-Ray based, MR based, Nuclear Medicine based</td>
</tr>
<tr>
<td>Planning Features</td>
<td>Plan Entry and Target Selection, 3D Model Building, Advanced Visualization</td>
<td>Plan Entry and Target Selection, 3D Model Building, Advanced Visualization</td>
</tr>
<tr>
<td>Interfaces</td>
<td></td>
<td></td>
</tr>
<tr>
<td>View (Display) Features</td>
<td>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</td>
<td>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</td>
</tr>
<tr>
<td>Software Interface (GUI)</td>
<td>Blue style with chronological next/back task flow at the top of the screen. Image controls on the left. Planning information on the right.</td>
<td>Blue style with chronological next/back task flow at the top of the screen. Image controls on the left. Planning information on the right.</td>
</tr>
<tr>
<td>Programming Language</td>
<td>C++</td>
<td>C++</td>
</tr>
<tr>
<td>Scanner Interface Technology (to imaging devices)</td>
<td>Network Connectivity CD, DVD, USB DICOM or Stealth format Import Export in Stealth format</td>
<td>Network Connectivity CD, DVD, USB DICOM or Stealth format Import Export in Stealth format</td>
</tr>
<tr>
<td>Localization Technology</td>
<td>Optical (infra-red) Electro magnetic</td>
<td>Optical (infra-red) Electro magnetic</td>
</tr>
</tbody>
</table>
**Item**

<table>
<thead>
<tr>
<th>Subject Device</th>
<th>Predicate Device</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Subject Device</strong></td>
<td><strong>Predicate Device</strong></td>
</tr>
<tr>
<td>StealthStation System with Cranial v3.1.1 Software</td>
<td>K153660 StealthStation System with StealthStation Cranial v3.0 Software</td>
</tr>
</tbody>
</table>

**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 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.

Specific Mean Accuracy Values

- Positional Error – 1.16 mm
- Trajectory Error – 0.41 degrees

Imaging Modalities

- X-Ray based
- MR based
- Nuclear Medicine based

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.

Specific Mean Accuracy Values

- Position Error - ≤ 2.00 mm
- Trajectory Error - ≤ 2.0°

Imaging Modalities

- X-Ray based
- MR based
- Nuclear Medicine based
<table>
<thead>
<tr>
<th>Item</th>
<th>Subject Device</th>
<th>Predicate Device</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Patient Registration: PointMerge registration, Tracer registration, Touch-N-Go registration, StealthAiR registration, O-arm registration, Stereotactic Localizer Registration and StarFix Bone Anchor Registration</td>
<td>Patient Registration: PointMerge registration, Tracer registration, Touch-N-Go registration, StealthAiR registration, O-arm registration, Stereotactic Localizer Registration and StarFix Bone Anchor Registration</td>
</tr>
<tr>
<td><strong>Planning Features</strong></td>
<td>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</td>
<td>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</td>
</tr>
<tr>
<td><strong>View (Display) Features</strong></td>
<td>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</td>
<td>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</td>
</tr>
<tr>
<td><strong>Software Interface (GUI)</strong></td>
<td>Blue style with chronological next/back task flow at the top of the screen. Image controls on the left. Planning information on the right.</td>
<td>Blue style with chronological next/back task flow at the top of the screen. Image controls on the left. Planning information on the right.</td>
</tr>
<tr>
<td><strong>Programming Language</strong></td>
<td>C++</td>
<td>C++</td>
</tr>
<tr>
<td><strong>Scanner Interface Technology (to imaging devices)</strong></td>
<td>Network Connectivity CD, DVD, USB DICOM Import DICOM Export</td>
<td>Network Connectivity CD, DVD, USB DICOM Import DICOM Export</td>
</tr>
<tr>
<td><strong>Localization Technology</strong></td>
<td>Optical (infra-red) Electromagnetic Mechanical based stereotactic</td>
<td>Optical (infra-red) Electromagnetic Mechanical based stereotactic</td>
</tr>
</tbody>
</table>

**X. Identification of Legally Marketing Devices**
StealthStation® System with Synergy Cranial Software (K150216)
StealthStation® System with Cranial Software (K150663)
XI. **Discussion of the Performance Testing**

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

<table>
<thead>
<tr>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
</tr>
</tbody>
</table>

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:

<table>
<thead>
<tr>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Software Development Life Cycle</td>
</tr>
<tr>
<td>Software Risk Assessment</td>
</tr>
<tr>
<td>Software Configuration Management and Version Control</td>
</tr>
</tbody>
</table>

XII. **Conclusions**

The StealthStation Cranial software has been shown through testing and comparison to be substantially equivalent to the identified predicate devices.