



March 31, 2017

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Medtronic Navigation, Inc.
Tia Fushimi-Bain
Sr Regulatory Affairs Specialist
826 Coal Creek Circle
Louisville, Colorado 80027

Re: K162309

Trade/Device Name: Stealthstation S8 System Platforms and StealthStation Cranial Software
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: HAW, OLO, PGW
Dated: August 16, 2016
Received: August 17, 2016

Dear Ms. Fushimi-Bain:

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. 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Michael J. Hoffmann -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K162309

Device Name

StealthStation S8 System with StealthStation Cranial software

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

The user should consult the "Navigational Accuracy" section of the User Manual to assess if the accuracy of the system is suitable for their needs.

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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Indications for Use

510(k) Number (if known)

K162309

Device Name

StealthStation S8 System Platform

Indications for Use (Describe)

The StealthStation™ System is intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. The StealthStation™ System 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, a long bone, or vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.

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)

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510(k) Summary**March 31, 2017**

- I. Company:** Medtronic Navigation, Inc.
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Senior Regulatory Affairs Specialist
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- II. Proprietary Trade Name:** StealthStation™ S8 Platform with StealthStation™ Cranial Software
- III. Common Name:** Stereotaxic Instrument
- IV. Classification Name:** Stereotaxic Instrument (21 CFR 882.4560)
- V. Classification:** Class II
- VI. Product Code:** HAW
- VII. Product Description:** The StealthStation™ S8 System, with StealthStation™ Cranial v1.0.0 software helps guide surgeons during cranial surgical procedures such as biopsies, tumor resections, and shunt and lead placements. The StealthStation™ Cranial v1.0.0 software (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. 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.
- VIII. Indications for Use:**
The StealthStation™ System is intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. The StealthStation™ System 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, a long bone, or vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.

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 user should consult the "Navigational Accuracy" section of the User Manual to assess if the accuracy of the system is suitable for their needs.

IX. Identification of Legally Marketed Devices (Predicate Devices):

K153660 - Synergy Cranial 3.0 Software

K050438 - StealthStation™ System Update

K133444 - StealthStation™ System Update

X. Comparison of the Technological Characteristics:

Item	Subject Device	Software Predicate	Platform Predicate
Intended Use	<p>Cranial Software The StealthStation® System, with StealthStation® Cranial software is designed as an aid for locating anatomical structures in either open or percutaneous neurosurgical procedures.</p> <p>StealthStation S8 Platform The StealthStation® System is intended as an aid for precisely locating anatomical structures in either open or percutaneous surgical procedures.</p>	<p>K153660, Synergy Cranial 3.0 Software The StealthStation® System, with StealthStation® Cranial software is designed as an aid for locating anatomical structures in either open or percutaneous neurosurgical procedures.</p>	<p>K050438, StealthStation™ System Update The StealthStation™ System is intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures.</p>

Item	Subject Device	Software Predicate	Platform Predicate
Indications for Use	<p>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.</p> <p>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</p> <p>The user should consult the "Navigational Accuracy" section of the User Manual to assess if the accuracy of the system is suitable for their needs.</p>	<p>K153660, Synergy Cranial 3.0 Software 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.</p> <p>This can include, but is not limited to, the following cranial procedures (including stereotactic frame-based and stereotactic frame alternatives-based procedures):</p> <ul style="list-style-type: none"> - 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 	<p>K050438, StealthStation™ System Update The StealthStation™ System is intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. The StealthStation™ System 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, a long bone, or vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.</p>
System Accuracy Requirement	Under representative worst-case configuration, the StealthStation S8 System with StealthStation Cranial v1.0.0 Software,	K153660, Synergy Cranial 3.0 Software Under representative worst-case configuration, the StealthStation®	Not Applicable

Item	Subject Device	Software Predicate	Platform Predicate
	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.	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.	
Imaging Modalities	X-Ray based, MR based, Nuclear Medicine based	K153660, Synergy Cranial 3.0 Software X-Ray based, MR based, Nuclear Medicine based	Not Applicable
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	K153660, Synergy Cranial 3.0 Software 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	Not Applicable
Exam-to-Exam Registration Features	Identity Merge Registration, Manual Merge Registration and Automatic Merge Registration	K153660, Synergy Cranial 3.0 Software Identity Merge Registration, Manual Merge Registration and Automatic Merge Registration.	Not Applicable
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)	K153660, Synergy Cranial 3.0 Software PointMerge® registration, Tracer™ registration, Touch-N-Go™ registration, StealthAiR® registration, O-arm® registration, Stereotactic Localizer Registration and StarFix™ Bone Anchor Registration	Not Applicable
Planning Features	Plan Entry and Target Selection 3D Model Building Advanced Visualization	K153660, Synergy Cranial 3.0 Software Plan Entry and Target Selection 3D Model Building Advanced Visualization	Not Applicable

Item	Subject Device	Software Predicate	Platform Predicate
	Create Patient Based Anatomical Coordinate Space Stereotactic Frame Settings Brain Atlas: Schaltenbrand-Wahren Atlas with Talairach Grid STarFix™ Designer Annotations	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	K153660, Synergy Cranial 3.0 Software 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	Not Applicable
Compatible Medtronic Optical Instrumentation	Medtronic instruments tracked via optical markers or LEDs located on instrument and patient trackers via the optical localizing system.	K153660, Synergy Cranial 3.0 Software Medtronic instruments tracked via optical markers or LEDs located on instrument and patient trackers via the optical localizing system	K050438 StealthStation™ System Update StealthStation S7 supports optical instrumentation compatible with StealthStation software via optical localization.
Compatible Medtronic EM Instrumentation	Medtronic instruments tracked via electromagnetic localization technology located within the instrument and patient trackers	K153660, Synergy Cranial 3.0 Software Medtronic instruments tracked via electromagnetic localization technology located within the instrument and patient trackers	K050438 StealthStation™ System Update StealthStation S7 supports EM instrumentation compatible with StealthStation software via EM localization.
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.	K153660, Synergy Cranial 3.0 Software Blue style with chronological next/back task flow at the top of the screen. Image controls on the left. Planning information on the right.	Not Applicable

Item	Subject Device	Software Predicate	Platform Predicate
Programming Language	C++	K153660, Synergy Cranial 3.0 Software C++	Not Applicable
Scanner Interface Technology (to imaging devices)	Network Connectivity CD, DVD, USB DICOM Import DICOM Export	K153660, Synergy Cranial 3.0 Software Network Connectivity CD, DVD, USB DICOM Import DICOM Export	Not Applicable
Optical Technology	Manufacturer: Identical (Northern Digital Inc.) Localizer: Vega	K153660, Synergy Cranial 3.0 Software Optical (infra-red)	K050438, StealthStation™ System Update Manufacturer: Northern Digital Inc. Localizer: Polaris
Electromagnetic Technology	Manufacturer: Identical (Medtronic Navigation, Inc.) Localizer: AxiEM III Emitter Types: Side, Flat	K153660, Synergy Cranial 3.0 Software Electromagnetic Mechanical based stereotactic	K050438, StealthStation™ System Update Manufacturer: Medtronic Navigation, Inc. Localizer: AxiEM Emitter Types: Side
Computer	Intel-based PC	Not Applicable	K050438, StealthStation™ System Update Intel-based PC
RFID Reader	Capability added to system. Functionality not yet available with this release	Not Applicable	Not Available
Network Connectivity	Connection Type: Standard Ethernet 2.4GHz and 5.0 GHz Wireless connection	Not Applicable	K050438, StealthStation™ System Update Connection Type: Standard Ethernet Connection and modem connection
Remote Service Connectivity	Remote service access providing capability for secure remote desktop service over high speed connection (Branded Remote Presence)	Not Applicable	Not Available
Operating System	Linux-based: Ubuntu	Not Applicable	K133444, StealthStation™ S7, i7, Fusion Debian Linux

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™ S8 Platforms to establish substantial equivalence of the system and verify that the device will perform as intended meeting all of the design inputs:

- AAMI/ANSI ES 60601-1:2012 - Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance (IEC 60601-1:2005, MOD)
- IEC 60601-1-2:2007 - Medical Electrical Equipment – Part 1-2: General requirements for safety; Electromagnetic Compatibility – Requirements and Tests
- Software Verification and Validation testing verifying the operating system software requirements are met and software performs as intended
- Hardware Verification testing ensuring the hardware requirements identified for the system are met and hardware performs as intended
- Usability Testing was conducted in accordance to FDA guidance “Applying Human Factors and Usability Engineering to Medical Devices” demonstrating that the usability and human factors requirements were adequately met.

The following table summarizes the testing conducted on the StealthStation™ S8 System with StealthStation™ Cranial v1.0.0 Software:

Description						
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 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 in a clinically relevant workflow.						
There were three distinct end-to-end worst-case configuration pathways identified for the localization types (optical, electromagnetic and mechanical) in StealthStation™ Cranial software. The test configurations included CT images with slice spacing and thickness of 1.25 mm and T2-weighted MR images with slice spacing and thickness of 1.0 mm. In the imaging protocol, we recommend slice spacing and thickness for CT and MR imaging to be 1.0 mm or less. The following table summarizes the performance of the StealthStation™ S8 System using StealthStation™ Cranial software with optical, electromagnetic (EM) and mechanical localization.						
Performance Validation	Positional Error (mm)			Trajectory Angle Error (degrees)		
	Mean	Standard Deviation	99% CI* Upper	Mean	Standard Deviation	99% CI* Upper
Cranial S8 System with Optical Localization Performance Validation	1.45	0.67	3.02	0.60	0.32	1.68

Cranial S8 System with EM Localization Performance Validation	0.84	0.37	1.69	0.47	0.25	1.24
Cranial S8 System with Mechanical Localization Performance Validation	1.48	0.47	2.58	0.39	0.31	1.12
*CI (confidence interval)						
Software verification and validation testing for each requirement specification. Design verification and validation was performed using the StealthStation™ S8 System with 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

Design verification and validation was performed using the StealthStation™ S8 System with 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.

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

XII.Conclusions

The StealthStation™ S8 Platforms with StealthStation™ Cranial software have been shown through comparison and testing to be substantially equivalent to the identified predicate devices.