DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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May 19, 2017

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

Re: K170018
Trade/Device Name: StealthStation™ S8 ENT Software
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: PGW
Dated: April 21, 2017
Received: April 24, 2017

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. 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,

Eric A. Mann -S
2017.05.19 09:23:52 -04'00'

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170018

Device Name
StealthStation™ S8 ENT Software

Indications for Use *(Describe)*
The StealthStation™ System, with StealthStation™ ENT software, is intended as an aid for locating anatomical structures in either open or percutaneous ENT 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 procedures:

- Functional endoscopic sinus surgery (FESS)
- Endoscopic skull base procedures
- Lateral skull base procedures

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.

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510(k) Summary

May 8, 2017

I. Company: Medtronic Navigation, Inc.
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II. Proprietary Trade Name: StealthStation™ S8 ENT Software

III. Common Name: Stereotaxic instrument

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

V. Classification: Class II

VI. Product Codes: PGW

VII. Product Description

The StealthStation™ ENT software helps guide surgeons during ENT procedures such as functional endoscopic sinus surgery (FESS), endoscopic skull base procedures, and lateral skull base procedures. The StealthStation™ ENT software runs on the StealthStation™ S8 Platform. The StealthStation system is an Image Guided System (IGS), comprised of a platform, clinical software, surgical instruments, and a referencing system (which includes patient and instrument trackers). The IGS tracks the position of instruments in relation to the surgical anatomy, known as localization, and then identifies this position on preoperative or intraoperative images of a patient.

The ENT software can display patient images from a variety of perspectives (axial, sagittal, coronal, oblique) and 3-dimensional (3D) renderings of anatomical structures can also be displayed. During navigation, the system identifies the tip location and trajectory of the tracked instrument on images and models the user has selected to display. The

surgeon may also use the ENT software to create and store one or more surgical plan trajectories before surgery and simulate progression along these trajectories. During surgery, the software can display how the actual instrument tip position and trajectory relate to the plan, helping to guide the surgeon along the planned trajectory. While the surgeon's judgment remains the ultimate authority, real-time positional information obtained through the StealthStation™ System can serve to validate this judgment as well as guide.

VIII. Indications for Use

The StealthStation™ System, with StealthStation™ ENT software, is intended as an aid for locating anatomical structures in either open or percutaneous ENT 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 procedures:

- Functional endoscopic sinus surgery (FESS)
- Endoscopic skull base procedures
- Lateral skull base procedures

IX. Identification of Legally Marketed Devices

Predicate: K153247-Fusion Compact Navigation System (ENT Software)
Reference: K162309 – StealthStation S8 with StealthStation S8 Cranial Software

X. Comparison of the Technological Characteristics

Item	Subject Device StealthStation™ S8 ENT Software	Predicate Device FUSION Compact™ Navigation System (K153247)	Reference Device Stealthstation S8 System Platforms and StealthStation Cranial Software (K162309)
Classification	Class II	Class II	Class II
Product Code	PGW	PGW	HAW, OLO, PGW
Intended/Indications for Use	The StealthStation™ System, with StealthStation™ ENT software, is intended as an aid for locating anatomical structures in either open or percutaneous ENT 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	The Medtronic FUSION Compact™ computer-assisted surgery system and its associated applications are intended as an aid for precisely locating anatomical structures in either open or percutaneous ENT 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 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

Item	Subject Device StealthStation™ S8 ENT Software	Predicate Device FUSION Compact™ Navigation System (K153247)	Reference Device Stealthstation S8 System Platforms and StealthStation Cranial Software (K162309)
	identified relative to images of the anatomy. This can include, but is not limited to, the following procedures: • Functional endoscopic sinus surgery (FESS) • Endoscopic skull base procedures • Lateral skull base procedures	the skull, can be identified relative to a CT or MR based model or digitized landmarks of the anatomy.	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.
Operating Principle	Electromagnetic	Electromagnetic	Optical Electromagnetic
Accuracy Testing	Under representative worst-case configuration the StealthStation S8 ENT Software v1.0.0, has demonstrated performance in 3D positional accuracy with a mean error ≤ 2.0 mm and in trajectory error ≤ 2.0 degrees. Specific Mean Accuracy Values Positional Error- 0.88mm Trajectory Error- 0.73°	Under representative worst-case configuration the Fusion Compact ENT Software, has demonstrated performance in 3D positional accuracy with a mean error ≤ 3.0 mm. Specific Mean Accuracy Values Positional Error- 2.41mm Trajectory Error- Not applicable	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. Specific Mean Accuracy Values Optical Results: Positional Error – 1.45mm Trajectory Error – 0.60° EM Results: Positional Error – 0.84mm Trajectory Error – 0.47°

Item	Subject Device StealthStation™ S8 ENT Software	Predicate Device FUSION Compact™ Navigation System (K153247)	Reference Device Stealthstation S8 System Platforms and StealthStation Cranial Software (K162309)
			Mechanical Results: Positional Error – 1.48mm Trajectory Error – 0.39°
Imaging Modalities	X-Ray based, MR based, Nuclear Medicine based	X-Ray based, MR based, Nuclear Medicine based	X-Ray based, MR based, Nuclear Medicine based
View (Display) Features	3D, 2D Anatomic Orthogonal (Coronal, Sagittal, Axial), Video Input, Virtual Endoscopic, Trajectory 1 and 2, Target Guidance, Trajectory Guidance, Probe's Eye, Look Ahead	3D, 2D Anatomic Orthogonal (Coronal, Sagittal, Axial), 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, Endoscopic
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	Identity Merge Registration, Manual Merge Registration and Automatic Merge Registration
Patient Registration Features	PointMerge® registration, Tracer™ registration, Touch registration (previously Touch-N-Go™)	PointMerge® registration, Tracer™ 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, 3D Model Building, Advanced Visualization	Not Available	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
Scanner Interface Technology (to imaging devices)	Network Connectivity CD, DVD, USB DICOM Import	Network Connectivity CD, DVD, USB DICOM Import	Network Connectivity CD, DVD, USB DICOM Import

Item	Subject Device StealthStation™ S8 ENT Software	Predicate Device FUSION Compact™ Navigation System (K153247)	Reference Device Stealthstation S8 System Platforms and StealthStation Cranial Software (K162309)
	DICOM Export	DICOM Export	DICOM Export
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.	Blue style with chronological next/back task flow at the top of the screen. Image controls on the left. Planning information on the right.	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++	C++
Compatible Platform	StealthStation S8 Platforms including the Planning Station	Fusion Compact Platform	StealthStation S8 Platforms including the Planning Station

XI. Discussion of the Performance Testing

Testing conducted demonstrates the software will perform as intended according to the outlined design requirements. The following testing was conducted on the StealthStation™ S8 ENT Software to establish substantial equivalence of the software and verify that the device will perform as intended meeting all of the design inputs:

- Software Verification and Validation testing using a production equivalent StealthStation S8 Platform verifying the software requirements are met and software performs as intended.
- Software Verification and Validation testing using a production equivalent StealthStation S8 Platform verifying that the software performs as intended when running on the StealthStation S8 Platform.
- 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 ENT v1.0.0 Software:

Description
Under representative worst-case configuration, the StealthStation S8 ENT 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 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.
Software verification and validation testing for each requirement specification.
Software verification and validation testing using a production equivalent StealthStation S8 Platform.
System integration performance testing for ENT 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 ENT software in laboratory and simulated use settings. The results 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 changes to the subject device, StealthStation S8 ENT Software include: software enhancement modifications to the patient registration feature set, the introduction of additional views displayed by the software, and the introduction of the planning feature set. Bench testing has been conducted to evaluate the overall performance of the software with these modifications and results confirm that the device performs as intended and in a similar manner compared to the predicate and reference devices.

The StealthStation S8 ENT software intended use, technology and performance are equivalent between the subject and predicate and reference devices. Verification and validation testing results confirm there are no new or different questions of safety or effectiveness. The changes do not represent a new intended use, and do not affect the control mechanism, or operating principle. The information presented in this submission supports the subject device to be as safe and effective as the predicate and reference devices, and therefore supports a determination of substantial equivalence.

The StealthStation S8 ENT Software has been shown through comparison and testing to be substantially equivalent to the identified predicate and reference devices.