DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 11, 2015

Medtronic Navigation, Inc.
Ms. Kaye E. Waite
Senior Regulatory Specialist
826 Coal Creek Circle
Louisville, Colorado 80027

Re: K150216
Trade/Device Name: StealthStation System with Synergy Cranial Software
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: HAW
Dated: May 11, 2015
Received: May 12, 2015

Dear Ms. 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,

Carlos L. Pena -S

Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine 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)*
K150216

Device Name
StealthStation System with Synergy Cranial Software

Indications for Use *(Describe)*
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

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

June 10, 2015

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

Contact: Kaye E. Waite
Senior Regulatory Affairs Specialist
Telephone Number: 720-890-3200
Fax Number: 720-890-3500

II. Proprietary Trade Name: StealthStation System with Synergy Cranial Software

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

IV. Classification: Class II, Stereotaxic Instrument

V. Product Code: HAW

VI. Product Description

The StealthStation System, with Synergy Cranial v2.2.7 software helps guide surgeons during cranial surgical procedures such as biopsies, tumor resections, and shunt placements. The Synergy Cranial v2.2.7 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. Synergy Cranial v2.2.7 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.

VII. 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

VIII. Summary of the Technological Characteristics

Item	Subject Device (Synergy Cranial)	Predicate Device (Mach Cranial) ***StealthStation System Update - K050438***
Intended Use	The StealthStation® System, with Synergy® Cranial software is designed as an aid for precisely locating anatomical structures in either open or percutaneous neurosurgical procedures.	The StealthStation® System is intended as an aid for precisely locating anatomical structures in either open or percutaneous 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 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. For the optical-based and EM-based system, example procedures include, but are not limited to: - 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	The System has demonstrated accuracy with a mean positional error of 2mm and mean trajectory error of 2 degrees	The System has demonstrated accuracy with a mean positional error of 2mm and mean trajectory error of 2 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 Patient Registration	Exam-to-Exam Registration Patient 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
View (Display) Features	Ultrasound Video In, Ultrasound Overlay, 3D, Anatomic Orthogonal, Trajectory 1 and 2, Target Guidance, 2D Trajectory Guidance, Probes Eye, Look Ahead, Microscope Injection, Video Input	Ultrasound Video In, Ultrasound Overlay, 3D, Anatomic Orthogonal, Trajectory 1 and 2, Target Guidance, 2D 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.	Basic gray and black style with 4 main tasks and tab interface to access tools. Controls on the right.
Programming Language	C++	C++
Localization Technology	Optical (infra-red) Electromagnetic	Optical (infra-red) Electromagnetic

IX. Identification of Legally Marketing Device (Predicate Device)

StealthStation System Update (K050438)

X. Discussion of the Performance Testing

The following table summarizes the testing conducted on the StealthStation System with Synergy Cranial v2.2.7 software:

Description
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. This performance was determined using an anatomically representative phantom and utilizing a subset of system components and features that represent the worst-case combination of all potential system components. The test configuration included CT images with slice spacing and thickness of 1.0 mm, and T1-weighted MR images with slice spacing and thickness of 1.5 mm.
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 System with Synergy Cranial v2.2.7 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.

XI. Conclusions

The non-clinical data support the safety of the device and the software verification and validation demonstrate that the StealthStation System with Synergy Cranial v2.2.7 software should perform as intended in the specified use conditions. The non-clinical data demonstrate that the StealthStation System with Synergy Cranial 2.2.7 software performs comparably to the predicate device for the same intended use.