DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

September 14, 2016

Medtronic Navigation, Inc.
Ms. Augusta Henao
Senior Regulatory Affairs Specialist
826 Coal Creek Circle
Louisville, Colorado 80027

Re: K153660
Trade/Device Name: StealthStation System with StealthStation Cranial Software
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: HAW
Dated: August 12, 2016
Received: August 15, 2016

Dear Ms. Henao:

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)*
K153660

Device Name
StealthStation System with StealthStation Cranial Software

Indications for Use *(Describe)*
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 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.

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510(k) Summary

September 13, 2016

I. Company:

Medtronic Navigation, Inc.
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Senior Regulatory Affairs Manager
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II. Proprietary Trade Name: StealthStation® System with StealthStation® Cranial Software

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

IV. Classification: Class II, Stereotaxic Instrument

V. Product Codes: HAW

VI. Product Description

The StealthStation® System, with StealthStation® Cranial v3.0 software helps guide surgeons during cranial surgical procedures such as biopsies, tumor resections, and shunt and lead placements. The StealthStation® Cranial v3.0 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 v3.0 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 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 for their needs.

VIII. Summary of the Technological Characteristics

Item	Subject Device (StealthStation® System with StealthStation® Cranial v3.0 Software)	Predicate Devices
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.	**Synergy® Cranial v2.2.7 Software - K150216** The StealthStation® System, with Synergy® Cranial software is designed as an aid for precisely locating anatomical structures in either open or percutaneous neurosurgical procedures.
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.	**Synergy® Cranial v2.2.7 Software - K150216** 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.

Item	Subject Device (StealthStation® System with StealthStation® Cranial v3.0 Software)	Predicate Devices
	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 for their needs	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
System Accuracy Requirement	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.	**Synergy® Cranial v2.2.7 Software - K150216** 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.
Imaging Modalities	X-Ray based, MR based, Nuclear Medicine based	**Synergy® Cranial v2.2.7 Software - K150216** 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	**Synergy® Cranial v2.2.7 Software - K150216** 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
Exam-to-Exam Registration Features	Identity Merge Registration, Manual Merge Registration and Automatic Merge Registration.	**Synergy® Cranial v2.2.7 Software - K150216** Identity Merge Registration, Manual

Item	Subject Device (StealthStation® System with StealthStation® Cranial v3.0 Software)	Predicate Devices
		Merge Registration and Automatic Merge Registration.
Patient Registration Features	PointMerge registration, Tracer registration, Touch-N-Go registration, StealthAiR registration, O-arm registration, Stereotactic Localizer Registration and StarFix Bone Anchor Registration	**Primary Predicate:** **Synergy® Cranial v2.2.7 Software - K150216** PointMerge registration, Tracer registration, Touch-N-Go registration, StealthAiR registration and O-arm registration **Secondary Predicate:** **Natrex™ Device for StealthStation System K992927** Stereotactic Localizer Registration
Planning Features	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	**Primary Predicate:** **Synergy® Cranial v2.2.7 Software - K150216** Plan Entry and Target Selection 3D Model Building Advanced Visualization **Secondary Predicate:** **Natrex™ Device for StealthStation® System K992927** Stereotactic Localizer Registration Plan Entry and Target Selection Create Patient Based Anatomical Coordinate Space Stereotactic Frame Settings Brain Atlas: Schaltenbrand-Wahren Atlas with Talairach Grid 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	**Primary Predicate:** **Synergy® Cranial v2.2.7 Software - K150216** Microscope Navigation: Zeiss, Leica Ultrasound Navigation: Aloka and Sonosite Medtronic O-arm **Secondary Predicate:** **Natrex™ Device for StealthStation® System K992927** Stereotactic Frame Systems: Integra BRW/CRW and Leksell
Software Interface (GUI)	Blue style with chronological next/back task flow at the top of the screen. Image controls on the left. Planning	**Synergy® Cranial v2.2.7 Software - K150216** Blue style with chronological next/back

Item	Subject Device (StealthStation® System with StealthStation® Cranial v3.0 Software)	Predicate Devices
	information on the right.	task flow at the top of the screen. Image controls on the left. Planning information on the right.
Programming Language	C++	**Synergy® Cranial v2.2.7 Software - K150216** C++
Scanner Interface Technology (to imaging devices)	Network Connectivity CD, DVD, USB DICOM Import DICOM Export	**Synergy® Cranial v2.2.7 Software - K150216** Network Connectivity CD, DVD, USB DICOM or Stealth format Import Export in Stealth format
Localization Technology	Optical (infra-red) Electromagnetic Mechanical based stereotactic	**Primary Predicate:** **Synergy® Cranial v2.2.7 Software - K150216** Optical (infra-red) Electromagnetic **Secondary Predicate:** **Natrex™ Device for StealthStation System K992927** Optical (infra-red), Mechanical based stereotactic

IX. Identification of Legally Marketed Devices

StealthStation® System with Synergy Cranial Software (K150216)
Natrex Device for StealthStation® System (K992927)

X. Discussion of the Performance Testing

The following table summarizes the testing conducted on the StealthStation® System with StealthStation® Cranial v3.0 Software:

Description
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. The positional error is defined as the Euclidean distance from target to instrument tip at final point of insertion. The trajectory angle error is the angle between the planned surgical trajectory and trajectory of the neurosurgical instrument at final point of insertion. Depending on the surgical procedure and the particular neurosurgical instruments used, the resulting navigational accuracy may be negatively impacted.

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.

The test configuration for stereotactic frame-based, Nexframe®, and STarFix™ procedures 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. The following table summarizes the performance of the StealthStation® System using Cranial software with compatible stereotactic hardware platforms.

Performance Validation	**Positional Error (mm)**			**Trajectory Angle Error (degrees)**		
	Mean	Standard Deviation	99%CI* Upper Bound	Mean	Standard Deviation	99%CI* Upper Bound
Cranial 3.0 Stereotactic Frame System Performance Validation	1.57	0.63	3.04	0.52	0.34	1.31
Cranial 3.0 with Nexframe® System Performance Validation	1.65	0.50	2.81	0.68	0.31	1.40
Cranial 3.0 with STarFix™ System Performance Validation	1.08	0.54	2.34	0.70	0.42	1.68

*CI (Confidence Interval)

The test configuration for procedures using electromagnetic localization 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. The following table summarizes the performance of the Cranial software on the StealthStation System with electromagnetic (EM) localization.

Performance Validation	**Positional Error (mm)**			**Trajectory Angle Error (degrees)**		
	Mean	Standard Deviation	99%CI* Upper Bound	Mean	Standard Deviation	99%CI* Upper Bound
Cranial 3.0 with EM Localization System Performance Validation	1.67	0.82	3.91	1.31	0.55	2.73

*CI (Confidence Interval)

Medtronic developed a test method to simulate clinical configurations and workflows to derive this summary of performance. Due to the uniqueness of this test method, the performance results presented may not be comparable to results derived from other test methods or other medical devices.

Software verification and validation testing for each requirement specification. Design verification and validation was performed using the StealthStation® System with StealthStation® Cranial v3.0 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

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 StealthStation® Cranial v3.0 software should perform as intended in the specified use conditions. The non-clinical data demonstrate that the StealthStation® System with StealthStation® Cranial v3.0 software performs comparably to the predicate devices for the same intended use.