510(k) Summary

K133444

JUL 2 5 2014

January 2, 2014

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 Waite
Regulatory Affairs Specialist
Telephone Number: 720-890-2182
Fax Number: 720-890-3709

II. **Proprietary Trade Name**: StealthStation® System

III. **Common Name**: Stereotaxic Instrument

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

V. **Classification**: Class II (21 CFR 882.4560)

VI. **Product Code**: HAW, OLO

VII. **Product Description:**
The StealthStation® System includes hardware and software that enables real-time surgical navigation using radiological patient images. The navigation system creates a translation map between points in the patient anatomy and the corresponding points on radiologic images of the patient. Once this map is established (through a process called registration), the software can display the relative position of a tracked instrument to a representation of the patient's anatomy. In this way the images can help guide the surgeon's planning and approach. Prior to operating, the surgeon may then create, store, and simulate progression along one or more surgical trajectories. As an aid to visualization, the surgeon may also create and manipulate one or more 2D or 3D models of the anatomy. During surgery, the system tracks the position of specialized surgical instruments in or on the patient anatomy and continuously updates the instrument position on these images either by optical tracking or electromagnetic tracking.

The operating system is software that controls the execution of programs, and that provides services such as resource allocation, scheduling, input/output control, and data management. This includes managing computer system hardware and software resources and providing a common set of services for software applications to interface with computing hardware.

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-based or MR-based model, fluoroscopy images, or digitized landmarks of the anatomy.

IX. Identification of Legally Marketing Devices (Predicate Devices)

- StealthStation® System Update (K050438)

X. Comparison of the Technological Characteristics:

The subject of this 510(k) is the StealthStation® System with an off-the-shelf operating system, which represents a minor modification to the StealthStation® System predicate device (K050438). The difference between the predicate and the subject device is the change to the operating system from proprietary to off-the-shelf. No changes have been made to the StealthStation® operating principle or hardware due to the change to the operating system.

Item	Subject Devices	Predicate Devices
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.	***StealthStation System Update - K050438*** 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. Includes a list of clinical procedures.
Operating Principle (Tracking Method)	Identical	***StealthStation System Update - K050438*** Optical (infra-red) EM
Control Mechanism (Hardware)	Identical	***StealthStation System Update – K050438*** Digitizer/Localizer Computer Reference Frames

System Accuracy	Identical	***StealthStation System Update – K050438*** Stand-alone accuracy was reported in K050438 and will not change with the update to the operating system.
Operating System	Debian Linux	***StealthStation System Update - K050438*** Linux (GemOS)

The subject devices have the same intended use and technological characteristics as the predicate devices.

XI. Discussion of the Performance Testing

Testing was completed to ensure the functionality and compatibility with the identified Medtronic products. The following table summarizes the performance testing completed:

Test	Description	Result
Verification (Functional)	Provides confirmation that the design and implementation of the operating system and all operating system infrastructure correctly fulfills all product requirements	Verification successful, operating system fulfills all product requirements
Verification (Regression)	Provides confidence that after a change to a product, unchanged but vulnerable portions of the product have not been adversely affected.	Verification successful, product not adversely affected by change
Validation	Ensures that the product meets the needs of the end user.	Validation successful, product meets the needs of the end user

All tests passed, which demonstrates that the performance of the subject operating system is equivalent to that of the predicate device.

XII. Conclusions

The StealthStation® System with the Debian operating system has been shown through comparison and testing to be substantially equivalent to the identified predicate devices.

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

July 25, 2014

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

Re: K133444
Trade/Device Name: StealthStation® System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: HAW, OLO
Dated: June 26, 2014
Received: June 27, 2014

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" (21CFR 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)*
K133444

Device Name
StealthStation System

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-based 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Carlos L. Pena -S

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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