Food and Drug Administration
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April 21, 2017

Medtronic Navigation, Inc.
Monica Montanez
Principal Regulatory Affairs Specialist
826 Coal Creek Circle
Louisville, Colorado 80027

Re: K162655
    Trade/Device Name: StealthConnect Remote Viewing, Planning and Collaboration System
    Regulation Number: 21 CFR 882.4560
    Regulation Name: Stereotaxic Instrument
    Regulatory Class: Class II
    Product Code: HAW, LLZ
    Dated: March 21, 2017
    Received: March 22, 2017

Dear Ms. Montanez:

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)*
K162655

Device Name
StealthConnect Remote Viewing, Planning and Collaboration System

Indications for Use *(Describe)*
The StealthConnect® System is web-based software to remotely access the StealthStation® Cranial software for viewing, stereotactic surgery planning and collaborating by trained professionals such as physicians, technologists and nurses.

The StealthConnect® system has not been validated for primary diagnostic reading of Digital Imaging and Communications in Medicine (DICOM) images.

The StealthConnect® Remote Viewing, Planning and Collaboration System is an accessory to the StealthStation® System. It provides a web- based client interface to securely access encrypted storage of DICOM-compliant images via a LAN, and/or the internet using general-purpose computers, and by one or more authorized people. It provides for communication, storage, reformatting, rendering, and display of DICOM 3.0 compliant image data derived from various sources including CT and MRI. In addition, the system provides access to the surgical planning aspects of StealthStation® software, and can be used to set or review surgical plans for stereotactic surgeries that are compatible with and can be transferred to a StealthStation® System or any DICOM-compliant PACS system.

StealthConnect® is not to be used for mammography.

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.

510(k) Summary

Submitter:	Medtronic Navigation, Inc. 826 Coal Creek Circle Louisville, CO 80027
Contact Person:	Monica Montanez (Primary) Principal Regulatory Affairs Specialist Phone: (720) 890-2149 Fax: (763) 367-2076 E-mail: monica.r.montanez@medtronic.com Paul Smolenski (Alternate) Sr Manager Regulatory Affairs Phone: (978)698-6065 Fax: (978) 698-6069 E-mail: **paul.d.smolenski**@medtronic.com
Date Summary Prepared:	March 19, 2017
Device Trade Name:	StealthConnect Remote Viewing, Planning and Collaboration System
Device Common Name:	Stereotaxic Instrument (21 CFR 882.4560)
Device Classification:	Class II
Product Code:	HAW (Stereotaxic Instrument) LLZ (Image Processing System)
Classification Name:	21 CFR 882.4560 – Stereotaxic Instrument (HAW) 21 CFR 892.2050 – Picture Archiving and Communications System (LLZ)
Predicate Device:	K153660 – StealthStation Cranial v 3.0 (Primary) K984000 – StealthSERVER Image Storage and Communication System (Secondary) K161130 – ResolutionMD (Secondary)
Device Description:	The StealthConnect™ System enables web clients on users' computers to interact with a version of the existing StealthStation Cranial planning software that is running on a cloud-based server. The StealthConnect System enables:

- Secure remote access for one or more authorized users simultaneously, with each accessing different patients (multi-user concurrent planning sessions) via the server-based cranial software using a web browser on user-supplied, general-purpose client computers.
- A safe environment to access, control, and share images on a secure Health Insurance Portability and Accountability Act (HIPAA) and Health Information Technology for Economic and Clinical Health Act (HITECH) compliance-ready infrastructure.
- Authorization and access control, which is provided by integration with the user facility's Lightweight Directory Access Protocol (LDAP) or Windows Active Directory (AD) credentialing system (single sign on).

Indications for Use:

The StealthConnect™ System is web-based software to remotely access the StealthStation™ Cranial software for viewing, stereotactic surgery planning and collaborating by trained professionals such as physicians, technologists and nurses.

The StealthConnect™ system has not been validated for primary diagnostic reading of Digital Imaging and Communications in Medicine (DICOM) images.

The StealthConnect™ Remote Viewing, Planning and Collaboration System is an accessory to the StealthStation™ System. It provides a web- based client interface to securely access encrypted storage of DICOM-compliant images via a LAN, and/or the internet using general-purpose computers, and by one or more authorized people. It provides for communication, storage, reformatting, rendering, and display of DICOM 3.0 compliant image data derived from various sources including CT and MRI. In addition, the system provides access to the surgical planning aspects of StealthStation® software, and can be used to set or review surgical plans for stereotactic surgeries that are compatible with and can be transferred to a StealthStation™ System or any DICOM-compliant PACS system.

StealthConnect™ is not to be used for mammography.

Substantial Equivalence: The application of Medtronic StealthConnect™ System is substantially equivalent to the predicate(s) StealthStation with StealthStation Cranial v 3.0 (K153660); StealthSERVER Image Storage and Communication System (K984000) and ResolutionMD (K161130) in intended use, technology, design and physician use.

The Indications for Use for the subject Medtronic StealthConnect™ System are similar as the predicate(s). StealthConnect System is considered an accessory to the StealthStation with Cranial v3.0. Both devices are stereotactic planning devices. Calgary Scientific ResolutionMD is considered a secondary predicate since they share the underlying technology that enables the remote access, collaboration and concurrent use features.

Table 1: StealthConnect Predicate Device Comparison Table

Predicate Devices for 510(k)Feature/ Attribute	Subject Device StealthConnect® System (K162655)	(Primary) Predicate: StealthStation® System with StealthStation Cranial v 3.0 Software (K153660)	(Secondary)Predicate: StealthSERVER™ Image Storage and Communication System (K984000)	(Secondary) Predicate: Calgary Scientific's ResolutionMD™ (K161130)
Indications for Use	The StealthConnect™ System is web- based software to remotely access the StealthStation™ Cranial software for viewing, stereotactic surgery planning and collaborating by trained professionals such as physicians, technologists and nurses. The StealthConnect™ System has not been validated for primary diagnostic reading of DICOM images. The StealthConnect™ Remote Viewing, Planning and Collaboration System is an accessory to the StealthStation™ System. It provides a web- based client interface to securely access encrypted storage of DICOM-compliant images via a LAN, and/or the internet using general-purpose computers, and by one or more authorized people. It provides for communication, storage,	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 (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	The StealthServer™ Image Storage and Communication System is used to store and provide remote viewing access to diagnostic images via a LAN, the internet or modem. In addition, the system can be used to remotely set surgical plan for stereotactic surgeries that are compatible with and can be accessed by the StealthStation® Treatment Guidance Platform.	The ResolutionMD™ Web 2.9 software-based is intended for use as a diagnostic, review, and analysis tool by trained professionals such as physicians, technologists and nurses. When interpreted by a trained physician, reviewed images may be used as an element for diagnosis. It is the user's responsibility to ensure that the software is installed on appropriate hardware and that the image quality is suitable for the clinical application. Calgary Scientific recommends that the users of the ResolutionMD software consult the appropriate American College of Radiology Practice Guidelines pertaining to the anatomy and pathology being studied. The ResolutionMD™ is a software-based Picture Archiving and Communication System (PACS) used with general purpose computing hardware for the display and 3D visualization of medical image data. It provides for communication, storage, reformatting, rendering, and display of DICOM 3.0 compliant

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	reformatting, rendering, and display of DICOM 3.0 compliant image data derived from various sources including CT and MRI. In addition, the system provides access to the surgical planning aspects of StealthStation™ software, and can be used to set or review surgical plans for stereotactic surgeries that are compatible with and can be transferred to a StealthStation™ System or any DICOM-compliant PACS system. StealthConnect™ is not to be used for mammography.	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.		image data derived from various sources including CT and MRI. ResolutionMD is not to be used for mammography.
Prescription Use	Yes	Yes	Yes	Yes
Intended Users	Trained Professionals	Trained Professionals	Trained Professionals	Trained Professionals
Remote Use	Yes: Anywhere the end user can establish a secure connection to the hospital network	No: Hospital only	Yes: Anywhere the end user can establish a secure connection to the StealthSERVER Network Planning system inside and outside hospital.	Yes: By using the web browser over a network connection using a user supplied computer.

Predicate Devices for 510(k)Feature/ Attribute	Subject Device StealthConnect® System (K162655)	(Primary) Predicate: StealthStation® System with StealthStation Cranial v 3.0 Software (K153660)	(Secondary)Predicate: StealthSERVER™ Image Storage and Communication System (K984000)	(Secondary) Predicate: Calgary Scientific's ResolutionMD™ (K161130)
On Line Collaboration	Yes: Using PureWeb to share medical image data	No: Gather around the StealthStation System in hospital setting only	No: Only simultaneous access	Yes: The feature "Collaboration" is provided in ResolutionMD
Concurrent User Sessions	Yes: StealthConnect enables 5 users to simultaneously log on and access multiple patient data for stereotactic planning.	No: Single planning/navigating session	Yes: StealthSERVER allows up to 4 concurrent user sessions.	Yes: ResolutionMD allows multiple concurrent users
DICOM Import/Export via Query/Receive and Unattended	Yes: Import/Export DICOM images to/from its Cloud based patient database. Can receive DICOM transfers at any time (Unattended)	Yes: DICOM Import/Export/Query/Retrieve to/from its local patient database, and can receive DICOM transfers at any time if StealthStation is turned on and networked (Unattended).	Yes: DICOM Import/Export to its local patient database at any time	Yes: Import/Export DICOM images to its local database
Planning Features	StealthConnect provides: 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	Yes: The device is intended for detailed planning and treatment of patients: 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	Yes: Setting the target point and the entry point for a surgical procedure. 3D Model Building For Cranial and Spine procedures	No: The device is used for viewing images rather than stereotactic planning. However, when images are interpreted by a trained physician, the reviewed images may be used as an element for diagnosis and planning of treatment.

Predicate Devices for 510(k)Feature/ Attribute	Subject Device StealthConnect® System (K162655)	(Primary) Predicate: StealthStation® System with StealthStation Cranial v 3.0 Software (K153660)	(Secondary)Predicate: StealthSERVER™ Image Storage and Communication System (K984000)	(Secondary) Predicate: Calgary Scientific's ResolutionMD™ (K161130)
User Authorization and Authentication	Yes: Device requires user authentication and log on capabilities. StealthConnect ties into the hospital credentialing system.	No: Optional password protection	Yes: Device requires password protection using at the time C2 Security features based upon the requirements outlined in the U.S. Department of Defense Trusted Computer Systems	Yes: Device requires user authentication and provides log on capabilities.
2D Viewing	Yes: StealthConnect provides the same features Cranial v 3.0 offers for 2D standard viewing.	Yes: Utilizes StealthStation Cranial Software viewer for standard viewing to include tools for window/level, pan, zoom. Anatomic Orthogonal; Trajectory 1 and 2; Probes Eye, Look Ahead	Yes: 2 D Standard viewing	Yes: Subject device and predicates all have 2D Viewing features.
3D Viewing	Yes: StealthConnect provides the same features available in Cranial v 3.0 for 3 D volume rendering of the data set.	Yes: 3 D Volume rendering of the data set. Interactive controls lasso, wand threshold, annotations and segmentations tools.	Yes: 3D volume rendering of the data set and viewing	Yes: 3 D Volume rendering of the data set. Interactive controls for zoom, pan, rotate and window/level via mouse and keyboard controls.
Programming Language	C++/Javascript/HTML5	C++	Java	C++/Javascript/HTML
Imaging Modalities	X-Ray based, MR based Nuclear Medicine based	X-Ray based, MR based Nuclear Medicine based	X-Ray based, MR based	X-Ray based, MR based Nuclear Medicine based
System Accuracy Requirement	Mean Accuracy Values: Positional Error – 1.60mm Trajectory Error – 0.95 degrees	Mean Accuracy Values: Positional Error – 1.65mm Trajectory Error – 0.68 degrees	No: Navigational Accuracy was not required at the time	No: Device does not offer Stereotactic Planning

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Scanner Interface Technology (to imaging devices)	Network Connectivity CD, DVD, USB DICOM Import DICOM Export	Network Connectivity CD, DVD, USB DICOM Import DICOM Export	DICOM Import/Export (from PACS, scanners and StealthStation)	Network Connectivity DICOM Import DICOM Export
"Cybersecurity" Encryption of Patient Data	Yes: StealthConnect encrypts data in transit using TLS 1.2, and at rest using AES-256 with dedicated hardware key storage.	No: Data is not encrypted however the StealthStation running the software is located in a controlled access hospital environment	No: Data was not encrypted however security measures were addressed in the IFU.	Yes: ResolutionMD is typically secured using SSL.
Registration Features	StealthConnect provides Exam-to-Exam Registration: Identity Merge Registration, Manual Merge Registration and Automatic Merge Registration, Stereotactic Localizer Registration and StarFix Bone Anchor Registration. Other patient registration features in Cranial v 3.0 are not provided since they are for navigation.	Yes: Exam-to-Exam Registration: Identity Merge Registration, Manual Merge Registration and Automatic Merge Registration. Stereotactic Localizer Registration and StarFix Bone Anchor Registration. Patient Registration: PointMerge registration, Tracer registration, Touch-N-Go registration, StealthAiR registration, O-Arm registration	No: None needed to be provided for the planning purposes in effect at that time.	No: ResolutionMD does not offer registration features.

Performance Testing: Testing conducted demonstrates the product will perform as intended according to the outlined design requirements.   The following testing was conducted on the StealthConnect™ System to establish substantial equivalence of the system and verify that the device will perform as intended, meeting all of the design inputs:

- Usability Testing was conducted in accordance to IEC 62366 demonstrating that the usability and human factors requirements were adequately met.

- Software Verification and Validation testing verifying the software and hardware requirements are met and software performs as intended. Design verification and validation was performed using the StealthConnect server and 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. This includes the following:

    o Functional testing of the PureWeb component, a primary component of the predicate, ResolutionMD product demonstrated the functionality of the device is equivalent to the predicate.

    o Accuracy testing for planning components was conducted to ensure that the StealthConnect™ System met the prescribed requirement for accuracy as compared to the predicate, StealthStation Cranial v 3.0.

    o Display Effectiveness testing was performed to show that the images provided by the StealthConnect™ System, via the client applications, are sufficient to allow for the same level of stereotaxic surgical planning as provided by the predicate, Stealth Station with Cranial v 3.0 software.

The following table summarizes the quality assurance measures that were applied during the 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 since this is not considered new technology.

Conclusion: The non-clinical data support the safety of the device and the software verification and validation demonstrate that the StealthConnect™ Systemv1.0 should perform as intended in the specified use conditions. The non-clinical data demonstrate that the StealthConnect™ System is substantially equivalent to the predicate(s) StealthStation™ Cranial v 3.0; StealthSERVER™ and ResolutionMD.