DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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February 18, 2016

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

Re: K153247
Trade/Device Name: Fusion Compact Navigation System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: PGW
Dated: January 15, 2016
Received: January 19, 2016

Dear Mr. Sinha:

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

for Malvina 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)*
N/A

Device Name
Fusion Compact Navigation System

Indications for Use *(Describe)*

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 skull, can be identified relative to images 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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510(k) Summary

Submitter:

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Date Summary Prepared: January 15, 2016

Device Trade Name: Medtronic FUSION Compact™ Navigation System

Common Name: Ear Nose and Throat Stereotaxic Instrument

Device Classification: Class II

Product Code: PGW

Classification Name: 882.4560 – Stereotaxic Instrument

Predicate Device: K001284 – StealthStation System GoldenEye Micro-Magnetic Tracking System Option

Device Description:

The FUSION Compact™ system is a surgical guidance platform that supports use of special application software and associated instruments. The system reformats patient-specific CT or MR images acquired before surgery and displays them on-screen from a variety of perspectives (axial, sagittal, coronal). During surgery, the system tracks the position of specialized surgical probes in or on the patient anatomy and continuously updates the probe position on these images.

While the surgeon's judgment remains the ultimate authority, real-time positional information obtained through the FUSION Compact™ system can serve to validate this judgment as well as guide.

The FUSION Compact™ is an Electromagnetic-based navigation system, also known as an Image Guided System (IGS), which consists of clinical navigation software, a referencing system and

platform/computer hardware. Navigation tracks the position of navigated instruments in relation to the surgical anatomy and identifies this position on diagnostic or intraoperative images of the patient. The FUSION Compact™ system is modular and designed for use in medical office or operating room environments to conduct ENT procedures including Endoscopic Skull Base, Lateral Skull Base, and Functional Endoscopic Sinus Surgery (FESS) procedures. The FUSION Compact™ will utilize a monitor and PC all-in-one computer and a free-standing emitter holder option. The system supports the FUSION Compact™ 1.0 software application. The FUSION Compact™ will interface with the existing Electromagnetic (EM) localization system and existing ENT instruments.

Indications for Use: 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 skull, can be identified relative to images of the anatomy.

Substantial Equivalence: The FUSION Compact™ Navigation System is substantially equivalent to the following device:

- K001284 – StealthStation System GoldenEye Micro-Magnetic Tracking System Option

Table 1: FUSION Compact™ Predicate Device Comparison Table

	Subject Device	**Predicate**
	FUSION Compact™ Navigation System	**StealthStation GoldenEye (K001284)**
Classification	Class II	Class II
Product Code	PGW; 882.4560 – Stereotaxic Instrument	HAW; 882.4560 – Stereotaxic Instrument
Indications for Use	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	The StealthStation® GoldenEye 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

	Subject Device	Predicate
	FUSION Compact™ Navigation System	**StealthStation GoldenEye (K001284)**
	reference to a rigid anatomical structure, such as the skull, can be identified relative to a CT- or MR-based model or digitized landmarks of the anatomy.	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. Example procedures include but are not limited to: Cranial procedures: ■ Cranial biopsies ■ Tumor resections ■ Craniotomies/craniectomies ■ Skull base procedures ■ Thalamotomies/pallidotomies Spinal implant procedures, such as pedicle screw placement ENT procedures: ■ Transphenoidal procedures ■ Intranasal procedures ■ Orbital nerve decompression procedures Sinus procedures, such as maxillary antrostomies, ethmoidectomies, sphenoidotomies/sphenoid explorations, turbinate resections, and frontal sinusotomies
Operating Principle	The electromagnetic system collects measurements, determines position and orientation from each coil independently. The system transmits multiple magnetic fields within which the receive coils can be measured. A measurement for each coil within each transmitted field is used to	The electromagnetic system collects measurements, determines position and orientation from each coil independently. The system transmits multiple magnetic fields within which the receive coils can be measured. A measurement for each coil within each transmitted field is

	Subject Device	Predicate
	FUSION Compact™ Navigation System	**StealthStation GoldenEye (K001284)**
	determine the position and orientation of the coil. Measurement position and orientation for the coils are combined to determine the instrument position and orientation. Two measured positions, one from each coil, are utilized to determine position and orientation of a two coiled instrument. Three measured positions, one from each coil, are utilized to determine position and orientation of a three coiled instrument.	used to determine the position and orientation of the coil. Measurement position and orientation for the coils are combined to determine the instrument position and orientation. Two measured positions, one from each coil, are utilized to determine position and orientation of a two coiled instrument.
System Accuracy	Maximum error less than 3.0 mm at 95% confidence and 99.5% reliability.	Mean error is less than 2.0 mm with 99% confidence level of 4.0 mm
Computer and Software Technology		
Computer	Intel-Based PC Computer/Monitor all-in-one	Intel-Based PC
Operating System	Linux-Based: Ubuntu	Linux-based IRIX
Programming Language	C++	C++
Clinical Software Features	Imaging modalities, registration features, views (axial, coronal, sagittal)	Imaging modalities, registration features, views (axial, coronal, sagittal)
Electromagnetic Technology		
Electromagnetic Localization System	Medtronic Navigation AxiEM II Integrated	Medtronic Navigation AxiEM I Integrated
EM Configuration	EM field transmitter creates an EM field that is used to track and triangulate on the receive coils	EM field transmitter creates an EM field that is used to track and triangulate on the receive coils
Communication	USB 1.1 and 2.0	Serial Line (RS-232) Connection
Amplifier Technology	Class D	Class AB
Digitizer Box	CAC and NPI integrated into a single unit, portable and mountable	CAC and NPI provided in separate components as cart on wheels
Instrument ports	4-coils per port, 8 ports in total	2-coils per port, 6 ports in total

	Subject Device	Predicate
	FUSION Compact™ Navigation System	**StealthStation GoldenEye (K001284)**
Mobile Emitter	Emitter generates a low-intensity magnetic field to locate coils mounted within the tracker	Emitter generates a low-intensity magnetic field to locate coils mounted within the tracker
EM Mounting apparatus	Emitter Stand or Emitter Clamp	No mounting capability as this unit is incorporated into the cart and mounting is not needed.
Interfacing	Navigation Probe Interface (NPI) is configured for up to 4 coils per connection port. The instruments used are designed with 2 or 3 receive coils per instrument. Each of the receive coils is connected via the instrument cable to the instrument.	Navigation Probe Interface (NPI) is configured for up to 2 coils per connection port. The instruments used are designed with 2 receive coils per instrument. Each of the receive coils is connected via the instrument cable to the instrument connector, which is then connected to the NPI through a connection port.

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

- AAMI/ANSI ES 60601-1:2012 - Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance (IEC 60601-1:2005, MOD)
- IEC 60601-1-2:2014 - Medical Electrical Equipment – Part 1-2: General requirements for safety; Electromagnetic Compatibility – Requirements and Tests (2/2014)
- Software Verification and Validation testing verifying the software requirements are met and software performs as intended
- Hardware Verification testing ensuring the hardware requirements identified for the system are met and hardware performs as intended
- Accuracy Testing was conducted to ensure that the FUSION Compact met the prescribed requirement for accuracy. The FUSION Compact System demonstrates performance in 3D positional accuracy with a maximum error ≤ 3.0 mm. This performance was determined using a pegboard in a surgical office and OR simulated environment with all of the typical instruments and equipment seen in those environments. The upper bound

of the tip error data for both the surgical office and OR simulated environments was determined by statistical data analysis.

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

Conclusion:

The FUSION Compact™ Navigation System is similar in technological characteristics, imaging performance and indications for use as the predicate devices listed. These aspects, along with the functional testing conducted to the FDA recognized standards, demonstrate that FUSION Compact™ Navigation System does not raise new risks of safety and effectiveness when compared to the predicates.