June 26, 2020

Medtronic Navigation Inc.
Carey Brenner
Sr. Regulatory Affairs Specialist
826 Coal Creek Circle
Louisville, Colorado 80027

Re: K200723
Trade/Device Name: StealthStation S8 ENT Software 1.3, StealthStation FlexENT
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: PGW
Dated: March 18, 2020
Received: March 19, 2020

Dear Carey Brenner:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Michael J. Ryan
Director
DHT1C: Division of ENT, Sleep Disordered Breathing, Respiratory and Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200723

Device Name
StealthStation™ S8 ENT Software 1.3

Indications for Use *(Describe)*
The StealthStation FlexENT™ System, with the StealthStation™ ENT Software, is 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.
This can include, but is not limited to, the following procedures:
• Functional Endoscopic Sinus Surgery (FESS)
• Endoscopic Skull Base procedures
• Lateral Skull Base procedures

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200723

Device Name
StealthStation FlexENT™

Indications for Use *(Describe)*
The Medtronic StealthStation FlexENT™ 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

I. Company

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

Contact

Carey Brenner
Senior Regulatory Affairs Specialist
720-352-1146
carey.j.brenner@medtronic.com

K. Elizabeth Waite
Regulatory Affairs Manager
720-890-2182
elizabeth.waite@medtronic.com

II. Proprietary Trade Name:

StealthStation™ S8 ENT Software 1.3
StealthStation FlexENT™

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: PGW

VII. Product Description

The StealthStation FlexENT™ is an electromagnetic based surgical guidance platform that supports use of special application software (StealthStation™ S8 ENT Software 1.3 and associated instruments.

The StealthStation™ S8 ENT Software 1.3 helps guide surgeons during ENT procedures such as functional endoscopic sinus surgery (FESS), endoscopic skull base procedures, and lateral skull base procedures. StealthStation™ S8 ENT Software 1.3 functionality is described in terms of its feature sets which are categorized as imaging modalities, registration, planning, and views. Feature sets include functionality that contributes to clinical decision making and are necessary to achieve system performance.

Patient images can be displayed by the StealthStation™ S8 ENT Software 1.3 from a variety of perspectives (axial, sagittal, coronal, oblique) and 3-dimensional (3D) renderings of anatomical structures can also be displayed. During navigation, the system identifies the tip location and trajectory of the tracked instrument on images and models the user has selected to display. The surgeon may also create and store one or more surgical plan trajectories before surgery and simulate progression along these trajectories. During surgery, the software can display how the actual instrument tip position and trajectory relate to the plan, helping to guide the surgeon along the planned trajectory. While the surgeon's judgment remains the ultimate authority, real-time positional information obtained through the StealthStation™ System can serve to validate this judgment as well as guide. The StealthStation™ S8 ENT v1.3 Software can be run on both the StealthStation FlexENT™ and StealthStation™ S8 Platforms.

The StealthStation™ System is an Image Guided System (IGS), comprised of a platform (StealthStation FlexENT™ or StealthStation™ S8), clinical software, surgical instruments, and a referencing system (which includes patient and instrument trackers). The IGS tracks the position of instruments in relation to the surgical anatomy, known as localization, and then identifies this position on preoperative or intraoperative images of a patient.

VIII. Indications for Use

StealthStation™ S8 ENT Software 1.3

The StealthStation FlexENT™ system with the StealthStation™ ENT software, is 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.

This can include, but is not limited to, the following procedures:

- Functional Endoscopic Sinus Surgery (FESS)
- Endoscopic Skull Base procedures
- Lateral Skull Base procedures

StealthStation FlexENT™

The StealthStation FlexENT™ 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.

IX. Identification of Legally Marketed Devices (Predicate Devices)

Primary Predicate: K170018 - StealthStation™ S8 ENT Software 1.0
Predicate: K153247 - FUSION™ Compact

X. Comparison of the Technological Characteristics

Refer to the tables within this section for a comparison of the technological features of the subject devices compared to the predicate devices. The S8 Software 1.3 has been updated to enable compatibility with the StealthStation FlexENT™ platform. The StealthStation™ S8 ENT software 1.3 running on the StealthStation™ S8 Platforms, including FlexENT™ is equivalent to the predicate devices in technological characteristics and indications for use.

The StealthStation FlexENT™ is a new platform that utilizes the latest Medtronic localization system (AxiEM III). The EM mounting apparatus has been updated from the Fusion™ Compact version in order to be compatible with the Medtronic AxiEM III localization system. The instruments that are compatible with the StealthStation FlexENT™ system are the same Medtronic instruments as those compatible with the Fusion™ Compact. The StealthStation FlexENT™ platform is equivalent to the predicate device in technological characteristics and indications for use.

Bench testing has shown that as navigation devices, the subject devices are as functional as the predicate. As such, there are no different questions of safety and effectiveness.

StealthStation™ S8 ENT Software Version 1.3 as Compared to Primary Predicate Device

Feature/ Attribute	**Subject Device** **StealthStation™ S8 ENT Software v1.3**	**Primary Predicate** **K170018, StealthStation™ S8 ENT Software v1.0 Running on StealthStation™ S8 Platform**
Classification	Same	Class II
Product Code	Same	PGW

Feature/ Attribute	Subject Device StealthStation™ S8 ENT Software v1.3	Primary Predicate K170018, StealthStation™ S8 ENT Software v1.0 Running on StealthStation™ S8 Platform
Intended/ Indications for Use	**StealthStation™ ENT Software v1.3, Running on StealthStation FlexENT™** The StealthStation FlexENT™ System, with the StealthStation™ ENT software, is 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. This can include, but is not limited to, the following procedures: • Functional Endoscopic Sinus Surgery (FESS) • Endoscopic Skull Base procedures Lateral Skull Base procedures **StealthStation™ S8 ENT Software v1.3 , Running on StealthStation™ S8 Platform** Same	The StealthStation™ S8 System, with the StealthStation™ ENT software, is 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. This can include, but is not limited to, the following procedures: • Functional Endoscopic Sinus Surgery (FESS) • Endoscopic Skull Base procedures • Lateral Skull Base procedures

Feature/ Attribute	Subject Device StealthStation™ S8 ENT Software v1.3	Primary Predicate K170018, StealthStation™ S8 ENT Software v1.0 Running on StealthStation™ S8 Platform
Accuracy Testing	Under representative worst-case configuration, the StealthStation FlexENT™ and S8 Systems with StealthStation™ S8 ENT v1.3 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. Specific Mean Accuracy Values Results of Software running on StealthStation FlexENT™: Positional Error – 0.93mm Trajectory Error – 0.55° Results of Software running on StealthStation™ S8: Positional Error – 1.04mm Trajectory Error – 1.31°	Under representative worst-case configuration, the StealthStation™ S8 System with StealthStation™ ENT v1.0 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. Specific Mean Accuracy Values Results: Positional Error – 0.88mm Trajectory Error – 0.73°
Compatible instrumentation	Same	Medtronic instruments tracked via electromagnetic localization technology located within the instrument and patient trackers.
Imaging Modalities	Same	X-Ray based MR based Nuclear Medicine based
View (Display) Features	Same	3D, 2D Anatomic Orthogonal (Coronal, Sagittal, Axial), Video Input, Virtual Endoscopic, Trajectory 1 and 2, Target Guidance, Trajectory Guidance, Probe's Eye, Look Ahead
Exam-to-Exam Registration Features	Same	Identity Merge Registration, Manual Merge Registration and Automatic Merge Registration
Patient Registration Features	Same	PointMerge® registration, Tracer™ registration, Touch registration (previously Touch-n-Go™)

Feature/ Attribute	Subject Device StealthStation™ S8 ENT Software v1.3	Primary Predicate K170018, StealthStation™ S8 ENT Software v1.0 Running on StealthStation™ S8 Platform
Planning Features	Same	Plan Entry and Target Selection, 3D Model Building, Advanced Visualization
Scanner Interface Technology (to imaging devices)	Same	Network Connectivity CD, DVD, USB DICOM Import DICOM Export
Software Interface (GUI)	Same	Black and gray style with procedure task overview in left menu option and next/back task flow at bottom of the screen. Software controls for images, planning and instrument management are contained in a right side bar.
Programming Language	Same	C++
Compatible Platforms	StealthStation™ Platforms including S8, Planning Station, FlexENT™	StealthStation™ S8 Platforms

StealthStation FlexENT™ Platform as compared to Predicate Device

Item	Subject Device StealthStation FlexENT™ Platform	Predicate K153247, FUSION™ Compact Platform
Classification	Same	Class II
Product Code	Same	PGW

Item	Subject Device StealthStation FlexENT™ Platform	Predicate K153247, FUSION™ Compact Platform
Intended/ Indications for Use	Same	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.
Operating Principle (Tracking Method) Electromagnetic Technology including Localization System	Electromagnetic Manufacturer: Same Localizer: AxiEM III Emitter Types: Side, Flat	Electromagnetic Manufacturer: Medtronic Navigation, Inc. Localizer: AxiEM II Emitter Types: Side
Computer	Same	Intel-Based PC Computer/Monitor all-in-one, touch screen technology, video capture
Operating System	Same	Linux-based: Ubuntu
Network Connectivity	Same	Standard Ethernet
Instrument Tracking	Same	Receive Coils
Instrument ports	4-coils per port, 6 ports in total	4-coils per port, 8 ports in total
EM Mounting apparatus	FlexENT Articulating Arm mounted to FlexENT Cart, FlexENT Floor Stand, or surgical bed rail.	Emitter Stand and Emitter Clamp
Compatible instrumentation	Medtronic instruments tracked via electromagnetic localization technology located within the instrument and patient trackers.	General instruments for ENT procedures, navigated sinus dilation instrumentation, trackers, powered blades, suctioning devices

XI. Discussion of the Performance Testing

Testing conducted demonstrates the product will perform as intended according to the outlined design requirements. The following testing was conducted on the StealthStation FlexENT™ Platform to establish substantial equivalence of the system and verify that the device will perform as intended meeting all the design inputs. The subject devices met all the performance testing requirements:

- Electrical Emissions and Immunity 4th edition testing provided confirmation that the StealthStation FlexENT™ platform conforms to AAMI/ANSI ES 60601-1:2012 - Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance (IEC 60601-1:2005, MOD).

- Electrical, Mechanical, Thermal Safety testing confirmed that the StealthStation FlexENT™ platform conforms to IEC 60601-1-2:2014 - Medical Electrical Equipment – Part 1-2: General requirements for safety; Electromagnetic Compatibility – Requirements and Tests.

- Software Verification and Validation testing verified the operating system 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

- The StealthStation FlexENT™ platform and product labeling was tested for the intended user profiles, uses, and use environments in accordance to FDA guidance “Applying Human Factors and Usability Engineering to Medical Devices” demonstrating that the usability and human factors requirements were adequately met. The StealthStation FlexENT has been found to be adequately safe and effective for the intended users, uses and use environments.

For the software, Integration tests are executed as part of development tasks for every code change. These tests are executed and must pass prior to merging into the production code branch for formal testing. Verification & validation tests are then executed, and evidence of final passing execution is documented in the Verification & Validation Plan-Summary

The following table summarizes the testing conducted on the StealthStation FlexENT™ and the StealthStation™ S8 platforms with StealthStation™ ENT v1.3 Software.

Description

Testing was performed under the representative worst-case configuration, for the StealthStation™ S8 ENT 1.3 Software running on the StealthStation FlexENT™ and the StealthStation™ S8 platforms. Results 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 anatomically representative phantoms and utilizing a subset of system components and features that represent the worst-case combinations of all potential system components. The results show that the update to the StealthStation™ S8 ENT 1.3 Software running on the StealthStation FlexENT™ and the StealthStation™ S8 platforms do not impact overall system accuracy performance.

	Subject (StealthStation™ S8 ENT v1.3)		**Predicate (StealthStation™ S8 ENT v1.0)**
platform	**StealthStation FlexENT™**	**StealthStation™ S8**	**StealthStation™ S8**
	Positional Error (mm)		
Mean	0.93	1.04	0.88
Standard Deviation	0.47	0.51	0.48
99% Confidence Interval	2.02	2.23	2.39
	Trajectory Error (degree)		
Mean	0.55	1.31	0.73
Standard Deviation	0.29	0.44	0.45
99% Confidence Interval	1.22	2.34	2.52

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

The results of testing support the safety and effectiveness of the StealthStation ENT v1.3 software running on the StealthStation FlexENT and StealthStation S8 platforms and demonstrate that the software should perform as intended in the specified use conditions.

Bench testing has shown that as navigation devices, the subject devices are as functional as the predicate. As such, there are no different questions of safety and effectiveness.

Clinical testing was not considered necessary prior to release as this is not new technology.

XII. Conclusions

The StealthStation FlexENT™ Platform and StealthStation™ S8 ENT Software v1.3 have been shown through comparison and testing to be substantially equivalent to the identified predicate devices.