March 16, 2026

Medtronic Navigation, Inc.
Maulik Shah
Senior Regulatory Affairs Specialist
200 Medtronic Dr.
Lafayette, Colorado 80026

Re: K253395
Trade/Device Name: Stealth AXiS™ ENT clinical application
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: PGW
Dated: November 18, 2025
Received: November 18, 2025

Dear Maulik Shah:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

SHUCHEN PENG -S

Shu-Chen Peng, Ph.D.
Assistant Director
DHT1B: Division of Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253395

Please provide the device trade name(s).

Stealth AXiS™ ENT Clinical Application (9736551)

Please provide your Indications for Use below.

The Stealth AXiS™ Surgical System, with the Stealth AXiS™ ENT clinical application, is intended for precise positioning of surgical instruments and as an aid for locating anatomical structures in open, minimally invasive, and 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

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

November 18, 2025

I. Company:

Medtronic Navigation, Inc.
200 Medtronic Drive
Lafayette, CO 80026
Telephone Number: (720) 890-3160

Contact: Maulik Shah
Senior Regulatory Affairs Specialist
Telephone Number: (929) 350-7138
Email: maulik.shah2@medtronic.com

Carey Brenner (Alternate)
Principal Regulatory Affairs Specialist
Telephone Number: (720) 890-2185
Email : carey.j.brenner@medtronic.com

II. Proprietary Trade Name: Stealth AXiS™ ENT Clinical Application

III. **Common Name:** Ear, Nose, and Throat Stereotaxic Instrument

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

V. Classification: Class II

VI. **Product Code:** PGW (Ear, Nose, and Throat Stereotaxic Instrument)

VII. Predicate Devices:

The legally marketed predicate devices are identified below:

Subject Device	**Primary Predicate Device**
Stealth AXiS ENT Clinical Application	StealthStation S8 ENT Software v1.3 **K200723** S.E June 26, 2020

VIII. Device Description:

The Stealth AXiS ENT Clinical Application works in conjunction with the Stealth AXiS Surgical System, which consists of clinical software, surgical instruments, a referencing system, and platform/computer hardware. The Stealth AXiS™ ENT Clinical Application helps guide surgeons during ENT procedures such as functional endoscopic sinus surgery (FESS), endoscopic skull base procedures, and lateral skull base procedures. The system 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.

IX. Indications for Use:

The Stealth AXiS™ Surgical System, with the Stealth AXiS™ ENT clinical application, is intended for precise positioning of surgical instruments and as an aid for locating anatomical structures in open, minimally invasive, and 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

X. Comparison of Technological Characteristics:

A comparison of the technological characteristics of the subject and the predicate device is provided in the table below.

Table 1. Technological Comparison of Stealth AXiS ENT Clinical Application v1.0 (Subject) and StealthStation S8 ENT Application v1.3 (Predicate)

Technological Characteristic	**Stealth AXiS ENT Application v1.0** **Subject Device**	**StealthStation S8 ENT Application v1.3 (K200723)** **Predicate Device**	**Discussion**
Product Code	PGW	PGW	Same
Regulation Number	882.4560	882.4560	Same
Classification	Class II	Class II	Same
Intended Use / Indications for Use	The Stealth AXiS™ Surgical System, with the Stealth AXiS™ ENT clinical application, is intended for precise positioning of surgical instruments and as an aid for locating anatomical structures in open, minimally invasive, and 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:	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)	Equivalent The intended use/ indications for use of the predicate and subject device is the same. The predicate and subject devices share the same fundamental purpose – to assist clinicians through surgical navigation by aiding in precisely locating anatomical structures relative to the surgical instrument location. The subject device adds minimally invasive procedures. The inclusion of minimally invasive procedures does not represent a change in clinical application; it is added to reflect

	• Functional endoscopic sinus surgery (FESS) • Endoscopic skull base procedures • Lateral skull base procedures	• Endoscopic skull base procedures • Lateral skull base procedures	the ENT procedures that are performed through less invasive approaches for procedures. The subject device operates under the same principles as the predicate device. Therefore, the subject and predicate have the same intended use
System Accuracy Requirement	Under representative worst-case configuration, the Stealth AXiS Surgical System with Stealth AXiS ENT application, 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	Under representative worst-case configuration, the StealthStation S8 System with StealthStation ENT Software v1.3 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	Identical
Imaging Modalities	• X-Ray based • MR based • Nuclear Medicine based	• X-Ray based • MR based • Nuclear Medicine based	Identical
View (Display) Features	• 3D, 2D Anatomic Orthogonal (coronal, sagittal, axial) • Trajectory 1 and 2 • Target Guidance • Trajectory Guidance • Probes Eye • Look Ahead • Video Input	• 3D, 2D Anatomic Orthogonal (coronal, sagittal, axial) • Virtual Endoscopic • Trajectory 1 and 2 • Target Guidance • Trajectory Guidance • Probes Eye • Look Ahead • Video Input	Identical
Exam-to-Exam Registration Features	• Pre-Merge (previously Identity Merge) Registration • Manual Merge Registration • Automatic Merge Registration	• Identity Merge Registration • Manual Merge Registration • Automatic Merge Registration	Identical
Patient Registration Features	• Trace registration • Touch registration	• PointMerge® registration (referred to as Landmark registrations) • Trace registration • Touch registration	Equivalent The Patient Registration feature, PointMerge, available in the predicate StealthStation S8 ENT Clinical Application v1.3, has been removed from the subject device. Removing a Patient Registration feature does not impact on the intended use or technological characteristics of the device.
Planning Features	• Plan Entry and Target Selection • Model Building • Advanced Visualization	• Plan Entry and Target Selection • Model Building • Advanced Visualization	Equivalent Note: The ENT clinical application is capable of 2D and 3D models, same as the predicate, so the feature has been renamed “Model Building” to capture all capabilities.

Compatible Medtronic EM Instrumentation	Medtronic instruments tracked via Electromagnetic localization technology located within the instrument and patient trackers	Medtronic instruments tracked via Electromagnetic localization technology located within the instrument and patient trackers	Identical
Scanner Interface Technology (to imaging devices)	Network Connectivity CD, DVD, USB DICOM Import DICOM Export	Network Connectivity CD, DVD, USB DICOM Import DICOM Export	Identical

XI. Discussion of the Non-Clinical Testing:

Testing demonstrates that the software will perform as intended according to the outlined design requirements. The following testing was conducted on the Stealth AXiS™ ENT Clinical Application to verify that the device will perform as intended meeting all the design inputs:

- Under representative worst-case configuration, the Stealth AXiS Surgical System with Stealth AXiS ENT application, 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.
- Software Verification and Validation testing using a release candidate of the Stealth AXiS ENT Clinical application verifying the software requirements are met and software performs as intended.
- Software Verification and Validation testing using a release candidate of the Stealth AXiS ENT Clinical application verifying that the software performs as intended when running on the Stealth AXiS Surgical System.
- Usability Testing was conducted in accordance with FDA guidance "Applying Human Factors and Usability Engineering to Medical Devices" demonstrating that the usability and human factors requirements were adequately met.

XII. Discussion of the Clinical Testing

No clinical testing was performed.

XIII. Conclusion:

The indications for use have been slightly reworded to explicitly acknowledge minimally invasive procedures. The inclusion of minimally invasive procedures in the intended use does not represent a change in the clinical application; it is added to reflect the neurosurgical procedures that are performed through less invasive approaches. All the core navigation, imaging, planning, and display features remain identical. The Stealth AXiS ENT clinical application has been shown through comparison, testing, and clinical literature to be substantially equivalent to the identified predicate device.