March 26, 2026

Medtronic Navigation, Inc.
Victoria Baldock
Senior Regulatory Affairs Specialist
200 Medtronic Dr.
Lafayette, Colorado 80026

Re: K253379
Trade/Device Name: Stealth AXiS Cranial clinical application
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: HAW
Dated: February 11, 2026
Received: March 23, 2026

Dear Victoria Baldock:

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 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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,

JULIA E. SLOCOMB -S

Digitally signed by JULIA E. SLOCOMB -S
Date: 2026.03.26 13:49:01 -04'00'

for Jaime Raben, Ph.D.
Director
DHT5A: Division of Neurosurgical, Neurointerventional, and Neurodiagnostic Devices
OHT5: Office of Neurological and Physical Medicine 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K253379

Device Name
Stealth AXiS Cranial clinical application

Indications for Use *(Describe)*
The Stealth AXiS Surgical System, with the Stealth AXiS Cranial clinical application, is intended for precise positioning of surgical instruments and as an aid for locating anatomical structures in open, minimally invasive, and percutaneous neurosurgical 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 cranial procedures (including stereotactic frame-based and stereotactic frame alternatives-based procedures):
• Tumor resections
• General ventricular catheter placement
• Pediatric ventricular catheter placement
• Depth electrode, lead, and probe placement
• Cranial biopsies

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.

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"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

November 14, 2025

I. Company: Medtronic Navigation, Inc.
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Lafayette, CO 80026
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Senior Regulatory Affairs Specialist
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Carey Brenner (Alternate)
Principal Regulatory Affairs Specialist
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II. Proprietary Trade Name: Stealth AXiS™ Cranial Clinical Application

III. Common Name: Neurological Stereotaxic Instrument

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

V. Classification: Class II

VI. Product Code: HAW (Neurological Stereotaxic Instrument)

VII. Predicate Devices:
The legally marketed predicate and reference devices are identified below:

Device Type	Device
Subject Device	Stealth AXiS Cranial clinical application v1.0
Predicate Device	StealthStation S8 Cranial Software v2.0 (K212397, cleared December 22, 2021)
Reference Device	SureTune4 Software (DEN210003, approved August 23, 2021)

VIII. Device Description:
The Stealth AXiS™ Cranial clinical application works in conjunction with the Stealth AXiS™ Surgical System. The Stealth AXiS™ Cranial clinical application helps guide surgeons during cranial procedures such as biopsies, tumor resections, shunt placements and depth

electrode and probe placement. The system tracks the position of instruments in relation to surgical anatomy and identifies this position on diagnostic or intraoperative images of the patient.

Patient images are transferred to the system, and the Stealth AXiS™ Cranial clinical application displays the image of the patient anatomy from a variety of perspectives (axial, sagittal, coronal, oblique) and 3-dimensional (3D) renderings of anatomical structures. During navigation, the Stealth AXiS™ Surgical System identifies the tip location and trajectory of the tracked instrument on images and models the user has selected to display on the monitor. The surgeon may also create and store one or more surgical plan trajectories before surgery and simulate progression along these trajectories. During surgery, the Stealth AXiS™ Cranial clinical application can display how the actual instrument tip position and trajectory relate to the pre-surgical plan, helping to guide the surgeon along the planned trajectory.

IX. Indications for Use:

The Stealth AXiS™ Surgical System, with the Stealth AXiS™ Cranial clinical application, is intended for precise positioning of surgical instruments and as an aid for locating anatomical structures in open, minimally invasive, and percutaneous neurosurgical 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 cranial procedures (including stereotactic frame-based and stereotactic frame alternatives-based procedures):

- Tumor resections
- General ventricular catheter placement
- Pediatric ventricular catheter placement
- Depth electrode, lead, and probe placement
- Cranial biopsies

X. Comparison of Technological Characteristics:

A comparison of the technological characteristics of the subject, predicate, and reference devices is provided in the table below.

Table 1. *Technological Comparison of Stealth AXiS Cranial Clinical Application (subject), StealthStation S8 Cranial Software (predicate), and SureTune4 Software (reference)*

Technological Characteristic	**Stealth AXiS™ Cranial Clinical Application v1.0** **Subject Device**	**StealthStation S8 Cranial Software v2.0 (K212397)** **Predicate Device**	**SureTune4 Software (DEN210003)** **Reference Device**
Intended Use / Indications for Use	The Stealth AXiS™ Surgical System, with the Stealth AXiS™ Cranial clinical application, is intended for precise positioning of surgical instruments and as an aid for locating anatomical structures in open, minimally invasive, and percutaneous neurosurgical 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 cranial procedures (including stereotactic frame-based and stereotactic frame alternatives-based procedures): • Tumor resections • General ventricular catheter placement • Pediatric ventricular catheter placement • Depth electrode, lead, and probe placement • Cranial biopsies	The StealthStation™ System, with StealthStation™ Cranial Software, is intended as an aid for locating anatomical structures in either open or percutaneous neurosurgical 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 cranial procedures (including stereotactic frame-based and stereotactic frame alternatives-based procedures): • Tumor resections • General ventricular catheter placement • Pediatric ventricular catheter placement • Depth electrode, lead, and probe placement • Cranial biopsies	
System Accuracy Requirement	Under representative worst-case configuration, the Stealth AXiS™ Surgical System with Stealth AXiS™ cranial 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 Cranial 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	
Imaging Modalities	• X-Ray based • MR based • Nuclear Medicine based	• X-Ray based • MR based • Nuclear Medicine based	

Technological Characteristic	Stealth AXiS™ Cranial Clinical Application v1.0 Subject Device	StealthStation S8 Cranial Software v2.0 (K212397) Predicate Device	SureTune4 Software (DEN210003) Reference Device
View (Display) Features	• Ultrasound Video In • Ultrasound Overlay • 3D • 2D Anatomic Orthogonal • Trajectory 1 and 2 • Target Guidance • Trajectory Guidance • Probes Eye • Look Ahead • Microscope Injection • Video Input	• Ultrasound Video In • Ultrasound Overlay • 3D • 2D Anatomic Orthogonal • Trajectory 1 and 2 • Target Guidance • Trajectory Guidance • Probes Eye • Look Ahead • Microscope Injection • Video Input	
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	
Patient Registration Features	• Trace registration, • Touch registration • O-arm™ registration • Mechanical based registrations (Stereotactic Localizer Registration)	• PointMerge® registration (referred to as Landmark registrations) • Trace registration • Touch registration • StealthAiR® registration • O-arm™ registration • Mechanical based registrations (Stereotactic Localizer Registration and StarFix™ Bone Anchor Registration)	
Planning Features	• Model Building (2D and 3D) • Tractography, including fiber tracts with Enhanced CSD techniques with automatically generated tracts (autotracts) • Plan Entry and Target Selection • Advanced Visualization • Create Patient Based Anatomical Coordinate Space • Stereotactic Frame Settings • Brain Atlas: 3D atlas (Paris and AHEAD)	• Model Building (2D and 3D) • Tractography, including fiber tracts with Standard DTI and Enhanced CSD techniques • Plan Entry and Target Selection • Advanced Visualization • Create Patient Based Anatomical Coordinate Space • Stereotactic Frame Settings • Brain Atlas: 2D atlas (Schaltenbrand- Wahren Atlas with Talairach Grid) • STarFix™ Designer Annotations	• Brain Atlas: 3D atlas (Paris)

Technological Characteristic	Stealth AXiS™ Cranial Clinical Application v1.0 Subject Device	StealthStation S8 Cranial Software v2.0 (K212397) Predicate Device	SureTune4 Software (DEN210003) Reference Device
Interfaces with Medical Devices	Medtronic O-arm™ O2 Imaging System Medtronic Stealth Autoguide™ System Microscope Navigation: Zeiss, Leica Ultrasound Navigation: GEHC bkActiv and Craniotomy Transducer Stereotactic Frame Systems: Inomed ZD (previously Fischer ZD), Integra CRW Stereotactic System, Elekta Leksell, Nexframe™ Stereotactic System	Medtronic O-arm™ O2 Imaging System Medtronic Stealth Autoguide™ System Microscope Navigation: Zeiss, Leica Ultrasound Navigation: Aloka, Sonosite Stereotactic Frame Systems: Fischer ZD, Fischer RM, Integra CRW Stereotactic System, Elekta Leksell Nexframe™ Stereotactic System, and STarFix™Platform System	
Compatible Medtronic Optical Instrumentation	Medtronic instruments tracked via optical markers or LEDs located on instrument and patient trackers via the optical localizing system.	Medtronic instruments tracked via optical markers or LEDs located on instrument and patient trackers via the optical localizing system.	
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	
Scanner Interface Technology (to imaging devices)	Network Connectivity CD, DVD, USB DICOM Import DICOM Export	Network Connectivity CD, DVD, USB DICOM Import DICOM Export	

XI. Discussion of Nonclinical Testing:

The testing conducted on the Stealth AXiS™ Cranial clinical application included:

- Under representative worst-case configuration, the Stealth AXiS™ Surgical System with Stealth AXiS™ Cranial clinical application has demonstrated performance in 3D positional accuracy with a mean error ≤ 2.0 mm and in trajectory angle accuracy with a mean error of ≤ 2.0 degrees.
- Software verification and validation testing verified the product requirements are met, and the device performs as intended.

- Summative usability validation was performed by representative users. The summative evaluations demonstrated the Stealth AXiS™ Cranial clinical application to be substantially equivalent for the intended user, uses, and use environments.

XII. Discussion of Clinical Testing:

No clinical testing was performed.

XIII. AI-enabled Device Summary:

Automatic Tractography (Autotracts)

The Automatic Tracts (Autotracts) feature in the Stealth AXiS Cranial clinical application uses AI and machine learning to automatically generate patient-specific white matter tracts from diffusion MRI images, streamlining pre-surgical planning. Users retain control by adjusting tract appearance via probability thresholds, manually cropping tracts as needed, and ultimately verifying tracts before proceeding.

Autotracts utilizes a locked U-Net-based convolutional neural network for brain segmentation, constrained spherical deconvolution for tractography, and a random forest classifier to filter tracts. Training and validation used hundreds of images from internal studies and public datasets, spanning normal and pathological cases, including expert-reviewed gold standard annotations.

Model training incorporated data augmentation, with validation performed on withheld datasets. Performance was assessed leveraging expert review to ensure reliability. The AI model is locked and does not update after deployment.

XIV. Conclusion:

The Stealth AXiS™ Cranial clinical application has been shown through comparison and testing to be substantially equivalent to the identified predicate.