October 17, 2025

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

Re: K251282
     Trade/Device Name: StealthStation™ S8 Spine Software v2.1
     Regulation Number: 21 CFR 882.4560
     Regulation Name: Stereotaxic Instrument
     Regulatory Class: Class II
     Product Code: OLO
     Dated: September 19, 2025
     Received: September 19, 2025

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 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 systems (QS) regulation (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,

Tejen D. Soni -S

For
Shumaya Ali, M.P.H.
Assistant Director
DHT6C: Division of Restorative,
   Repair, and Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number *(if known)*
K251282

Device Name
StealthStation™ S8 Spine Software v2.1

Indications for Use *(Describe)*

The StealthStation™ System, with StealthStation™ Spine Software, is intended as an aid for precisely locating anatomical structures in either open or percutaneous neurosurgical and orthopedic procedures in adult and skeletally mature pediatric (adolescent) patients. 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 spine or pelvis, can be identified relative to images of the anatomy.

This can include the following spinal implant procedures in adult patients, such as:
• Pedicle Screw Placement
• Iliosacral Screw Placement
• Interbody Device Placement

This can include the following spinal implant procedures in skeletally mature pediatric (adolescent) patients:
• Pedicle Screw Placement

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 - K251282

April 23, 2025

I.   **Company:**   Medtronic Navigation, Inc.
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Lafayette, CO 80026
Telephone Number: (720) 890-3160

      Contact: Victoria Baldock
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      Kyle Hoefling (Alternate)
Regulatory Affairs Director
Telephone Number: (760) 207-2432
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II.   **Proprietary Trade Name:**   StealthStation™ S8 Spine Software v2.1

III.   **Common Name:**   Orthopedic Stereotaxic Instrument

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

V.   **Classification:**   Class II

VI.   **Product Code:**   OLO (Stereotaxic Instrument)

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

Subject Device	Predicate Device	Reference Device
StealthStation™ S8 Spine Software v2.1	StealthStation™ S8 Spine Software v1.3 **K201189** S.E. May 29, 2020	Stryker Spine Guidance Software **K220593** S.E. May 27, 2022

VIII.   **Device Description:**
StealthStation S8 Spine Software helps guide surgeons during spine surgical procedures. The subject software works in conjunction with a navigation system, surgical instruments, a referencing system, and computer hardware. Navigation tracks the position of instruments in relation to the surgical anatomy and identifies this position on pre-operative or intraoperative images of the patient. The mouse, keyboard, touchscreen monitor, and footswitch of the

StealthStation platforms are used to move through the software workflow. Patient images are displayed by the software from a variety of perspectives (axial, sagittal, coronal, oblique) and 3-dimensional (3D) renderings. During navigation, the 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 and during 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.

IX.   **Indications for Use:**
The StealthStation™ System, with StealthStation™ Spine Software, is intended as an aid for precisely locating anatomical structures in either open or percutaneous neurosurgical and orthopedic procedures in adult and skeletally mature pediatric (adolescent) patients. 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 spine or pelvis, can be identified relative to images of the anatomy.

This can include the following spinal implant procedures in adult patients, such as:
- Pedicle Screw Placement
- Iliosacral Screw Placement
- Interbody Device Placement

This can include the following spinal implant procedures in skeletally mature pediatric (adolescent) patients:
- Pedicle Screw Placement

X.   **Comparison of the 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 StealthStation S8 Spine Software v2.1 (Subject), StealthStation S8 Spine Software v1.3 (Predicate), and Stryker Spine Q Guidance Software (Reference)

Technological Characteristic	StealthStation S8 Spine Software v2.1 (Subject)	StealthStation S8 Spine Software v1.3 (Predicate, K201189)	Stryker Spine Guidance Software (Reference, K220593)
Intended Use/ Indications for Use	The StealthStation™ System, with StealthStation™ Spine Software, is intended as an aid for precisely locating anatomical structures in either open or percutaneous neurosurgical and orthopedic procedures **in adult and skeletally mature pediatric (adolescent) patients**. 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 spine or pelvis, can be identified relative to images of the anatomy. This can include the following spinal implant procedures **in adult patients**, such as: • Pedicle Screw Placement • Iliosacral Screw Placement • Interbody Device Placement **This can include the following spinal implant procedures in skeletally mature pediatric (adolescent) patients:** • **Pedicle Screw Placement**	The StealthStation™ System, with StealthStation™ Spine Software, is intended as an aid for precisely locating anatomical structures in either open or percutaneous neurosurgical and orthopedic 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 spine or pelvis, can be identified relative to images of the anatomy. This can include the following spinal implant procedures, such as: • Pedicle Screw Placement • Iliosacral Screw Placement • Interbody Device Placement	The Stryker Q Guidance System, when used with the Spine Guidance software, is intended as a planning and intraoperative guidance system to enable open or percutaneous computer assisted surgery i**n adult and pediatric (adolescent) patients**. The system is indicated for any surgical procedure on the spine in which the use of computer assisted planning and surgery may be appropriate. The system can be used for intraoperative guidance where a reference to a rigid anatomical structure such as the spine, pelvis or skull can be identified. The system assists in the positioning of instruments for procedures on the spine and pelvis, including: • Screw Placement in the spine or pelvis
Product Code	OLO (Orthopedic Stereotaxic Instrument)	OLO (Orthopedic Stereotaxic Instrument)	OLO (Orthopedic Stereotaxic Instrument)
StealthStation Operating Principle (Tracking Method)	Optical (infra-red)	Optical (infra-red)	Optical (infra-red)
System Accuracy Requirement	Under representative worst-case Configuration, the StealthStation S8 Spine software v2.1, has demonstrated performance in 3D positional accuracy with a mean positional error of $\leq$ 2.0 mm and mean trajectory error of $\leq$ 2 degrees. Mean Accuracy Values (StealthAiR Spine): Positional Error – 1.01 mm Trajectory Error – 0.37 degrees	Under representative worst-case Configuration, the StealthStation S8 Spine software v1.3.0, has demonstrated performance in 3D positional accuracy with a mean positional error of $\leq$ 2.0 mm and mean trajectory error of $\leq$ 2 degrees. Mean Accuracy Values (StealthAiR Spine): Positional Error – 1.01 mm Trajectory Error – 0.37 degrees	The system has a mean accuracy of 2 mm for positional displacement and 2° for trajectory angle displacement. Accuracy values apply to tracking in the workspace.

Technological Characteristic	StealthStation S8 Spine Software v2.1 (Subject)	StealthStation S8 Spine Software v1.3 (Predicate, K201189)	Stryker Spine Guidance Software (Reference, K220593)
	Mean Accuracy Values (Overlapping Slices): Positional Error – 0.51 mm Trajectory Error – 0.41 degrees	Mean Accuracy Values (Overlapping Slices): Positional Error – 0.51 mm Trajectory Error – 0.41 degrees	
Imaging Modalities	X-Ray Based Imaging	X-Ray Based Imaging	N/A
Patient Registration Features	PointMerge Registration SurfaceMerge Registration FluoroMerge Registration Automatic 2D Image Registration Automatic 3D Image Registration StealthAiR Spine Automatic Registration	PointMerge Registration SurfaceMerge Registration FluoroMerge Registration Automatic 2D Image Registration Automatic 3D Image Registration StealthAiR Spine Automatic Registration	N/A
Planning Features	Plan Entry and Target Selection 3D Model Building Deformity Planning	Plan Entry and Target Selection 3D Model Building Deformity Planning	N/A
View (Display) Features	Look Sideways 3D Anatomic Orthogonal Trajecotry 1 and 2 Trajectory Guidance Look Ahead Probe's Eye AP and Lateral Synthetic AP and Lateral Maximum Intensity Projection Video Input	Look Sideways 3D Anatomic Orthogonal Trajecotry 1 and 2 Trajectory Guidance Look Ahead Probe's Eye AP and Lateral Synthetic AP and Lateral Maximum Intensity Projection Video Input	N/A
Software Interface (GUI)	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.	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.	N/A
Programming Language	C++	C++	N/A
Medical Device Interfaces	O-arm Imaging System Ziehm Vision FD Vario 3D C-Arm ISO-C 3D C-Arm Ziehm Vision RFD 3D C-Arm Stealth-Midas MR8	O-arm Imaging System Ziehm Vision FD Vario 3D C-Arm ISO-C 3D C-Arm Ziehm Vision RFD 3D C-Arm Stealth-Midas MR8	N/A

XI. Discussion of Nonclinical Testing:

The Verification and Validation activities of the StealthStation S8 Spine Software have not changed since the previous clearance of the device under K201189. A requirements review, risk assessment and clinical summary were performed to demonstrate that the proposed labeling changes met the design requirements, is safe and effective for use in skeletally mature pediatric (adolescent) patients population and is substantially equivalent to the predicate StealthStation S8 Spine Software v1.3 (K201189).

XII.   Discussion of Clinical Testing:

A retrospective clinical evaluation of published literature was performed to assess the safety and effectiveness of the StealthStation Navigation System for use in the skeletally mature pediatric (adolescent) patient population.

XIII.   Conclusion:

The StealthStation S8 Spine Software v2.1 with skeletally mature pediatric (adolescent) indications has been shown through comparison and clinical literature to be substantially equivalent to the identified predicate and reference devices.