May 29, 2020

Medtronic Navigation, Inc.
Jason Woehrle
Senior Regulatory Affairs Specialist
826 Coal Creek Circle
Louisville, Colorado 80027

Re: K201189
Trade/Device Name: Stealthstation S8 Spine Software v1.3.0
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: April 30, 2020
Received: May 1, 2020

Dear Jason Woehrle:

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,

Shumaya Ali, M.P.H.
Assistant Director
DHT6C: Division of Stereotaxic, Trauma
and Restorative Devices
OHT6: Office of Orthopedic 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)*

K201189

Device Name
StealthStation™ S8 Spine Software v1.3.0

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. 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:

o Pedicle Screw Placement
o Iliosacral Screw Placement
o Interbody Device 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.

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

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K201189

510(k) Summary

April 30, 2020

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

Contact: Jason Woehrle (Primary)
Senior Regulatory Affairs Specialist
Telephone Number: 949-399-1509
Fax Number: 720-890-3500

K. Elizabeth Waite (Alternate)
Regulatory Affairs Manager
Telephone Number: 720-890-2182
Fax Number: 720-890-3500

II. Proprietary Trade Name: StealthStation™ S8 Spine Software v1.3.0

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

IV. Classification: Class II, Stereotaxic Instrument

V. Product Codes: OLO

VI. Product Description

The StealthStation System, also known as an Image Guided System (IGS), is comprised of a platform, clinical software, surgical instruments and a referencing system. The IGS tracks the position of instruments in relation to the surgical anatomy and identifies this position on diagnostic or intraoperative images of a patient. The StealthStation Spine software helps guide surgeons during spine procedures such as spinal fusion and trauma treatments. StealthStation Spine Software functionality is described in terms of its feature sets which are categorized as imaging modalities, registration, planning, interfaces with medical devices, and views. Feature sets include functionality that contributes to clinical decision making and are necessary to achieve system performance.

VII. 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. 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:

o Pedicle Screw Placement
o Iliosacral Screw Placement
o Interbody Device Placement

VIII. Summary of the Technological Characteristics

Feature	StealthStation S8 Spine Software v1.3.0 (Subject Devices)	Predicate Devices (StealthStation S8 Spine Software v1.0.0) K170011
Intended 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.	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.
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. 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, can be identified relative to images of the anatomy. This can include, but is not limited to, the following procedures: • Pedicle Screw Placement •Iliosacral Screw Placement •Interbody Device 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, can be identified relative to images of the anatomy. This can include, but is not limited to, the following procedures: • Pedicle Screw Placement •Iliosacral Screw Placement •Interbody Device Placement
System Accuracy Requirements	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 ≤ 2.0 mm and mean trajectory error of ≤ 2 degrees.	Under representative worst-case Configuration, the StealthStation S8 Spine software v1.0.0, has demonstrated performance in 3D positional accuracy with a mean positional error of ≤ 2.0 mm and mean trajectory error of ≤ 2 degrees.

Feature	StealthStation S8 Spine Software v1.3.0 (Subject Devices)	Predicate Devices (StealthStation S8 Spine Software v1.0.0) K170011
	Mean Accuracy Values (StealthAiR Spine): Positional Error – 1.01 mm Trajectory Error – 0.37 degrees Mean Accuracy Values (Overlapping Slices): Positional Error – 0.51 mm Trajectory Error –0.41 degrees	Mean Accuracy Values: Positional Error – 1.30 mm Trajectory Error – 0.64 degrees
Imaging Modalities	X-Ray Based Imaging	X-Ray Based Imaging
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
Planning Features	Plan Entry and Target Selection 3D Model Building Deformity Planning	Plan Entry and Target Selection 3D Model Building Deformity Planning
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 Orbic 3D C-Arm	O-arm Imaging System Ziehm Vision FD Vario 3D C-Arm ISO-C 3D C-Arm Orbic 3D C-Arm
View/Display Features	Look Sideways 3D Anatomic Orthogonal Trajectory 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 Trajectory 1 and 2 Trajectory Guidance Look Ahead Probe's Eye AP and Lateral Synthetic AP and Lateral Maximum Intensity Projection Video Input
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	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,

Feature	StealthStation S8 Spine Software v1.3.0 (Subject Devices)	Predicate Devices (StealthStation S8 Spine Software v1.0.0) K170011
	images, planning and instrument management are contained in a right side bar.	planning and instrument management are contained in a right side bar.
Programming Language	C++	C++
Localization Technology	Optical (infra-red)	Optical (infra-red)

IX. Identification of Legally Marketing Devices

StealthStation S8 Spine Software v1.0.0 (K170011)

X. Discussion of the Performance Testing

The following table summarizes the testing conducted on the StealthStation S8 Spine Software v1.3.0

Description
Under representative worst-case configuration, the StealthStation S8 Spine Software v1.3.0 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. 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.
Software verification and validation testing for each requirement specification.
System integration performance testing for spine surgical procedures using anatomical phantoms.

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

XI. Conclusions

The StealthStation S8 Spine Software v1.3.0 has been shown through testing and comparison to be substantially equivalent to the identified predicate devices.