July 8, 2021

Medtronic Navigation
Victoria Baldock
Associate Regulatory Affairs Specialist
826 Coal Creek Circle
Louisville, Colorado 80027

Re: K211442
Trade/Device Name: StealthStation Spinous Process Clamps
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: May 7, 2021
Received: May 10, 2021

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 (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: 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211442

Device Name
StealthStation™ Spinous Process Clamps

Indications for Use *(Describe)*
The navigated instruments are specifically designed for use with the StealthStation™ System, which 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 a skull, a long bone, or vertebra can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.

When used with a Medtronic StealthStation™ Navigation System, the Spine Referencing fixation devices are intended to provide rigid attachment between patient and patient reference frame for the duration of the surgery.

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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510(k) Summary

May 07, 2021

I. Company:

Medtronic Navigation
826 Coal Creek Circle
Louisville, CO 80027
Telephone Number: (720) 890-3500

Contact: Victoria Baldock
Associate Regulatory Affairs Specialist
Telephone Number: (423) 863-5907
Email: tori.a.baldock@medtronic.com

Rishi Sinha (Alternate)
Regulatory Affairs Director
Telephone Number: (720) 890-2485
Email: rishi.k.sinha@medtronic.com

II. Proprietary Trade Name: StealthStation™ Spinous Process Clamps

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 devices are identified below:

Predicate	510(k) Clearance
Navigated CAPSTONE® Trials, CLYDESDALE® Trials, and CAPSTONE® & CLYDESDALE® Inserter	K131425

VIII. Product Description:
The Spinous Process Clamps are intended to provide rigid attachment between patient and patient reference frame for the duration of the surgery. The subject devices are designed for use with the StealthStation™ System and are intended to be reusable.

IX. Indications for Use:
The navigated instruments are specifically designed for use with the StealthStation™ System, which 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 a skull, a long bone, or vertebra can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.

When used with a Medtronic StealthStation™ Navigation System, the Spine Referencing fixation devices are intended to provide rigid attachment between patient and patient reference frame for the duration of the surgery.

X. Comparison of the Technological Characteristics:

The subject Spinous Process Clamps (Generation 4) utilize the same fundamental scientific technology and have the same mode of operation and functionality as the predicate Spinous Process Clamps (Generation 2) (K131425). The subject devices have equivalent materials and sterilization/reprocessing methods as the predicate (K131425). The changes in design features between the subject and the predate do not raise any new risks or any concerns about the safety and effectiveness. The subject devices also meet the established navigational accuracy requirements.

Table 1. Comparison of Technological Characteristics

Feature	Subject Devices StealthStation™ Spinous Process Clamps	Predicate Devices Navigated CAPSTONE® Trials, CLYDESDALE® Trials, and CAPSTONE® & CLYDESDALE® Inserter (K131425)
Intended Use	When used with a Medtronic StealthStation™ Navigation System, the Spine Referencing fixation devices are intended to provide rigid attachment between patient and patient reference frame for the duration of the surgery. The devices are intended to be reusable.	When used with a Medtronic StealthStation™ Navigation System, the Spine Referencing fixation devices are intended to provide rigid attachment between patient and patient reference frame for the duration of the surgery. The devices are intended to be reusable.
Indications for Use	The navigated instruments are specifically designed for use with the StealthStation™ System, which 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 a skull, a long bone, or vertebra can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.	The navigated instruments are specifically designed for use with the StealthStation™ System, which 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 a skull, a long bone, or vertebra can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.

Sterilization Method	Non-sterile, Steam sterilization, Reusable	Non-sterile, Steam sterilization, Reusable
Material	Titanium, 17-4 Stainless Steel, 300 Series Stainless Steel	Titanium, 17-4 Stainless Steel, 300 Series Stainless Steel
Thread Relief	Screw engaged threads with clamping mechanism at all time, due to full threaded screw design. Removal of two washer components due to screw changes.	Unengaged screw when clamps are open, due to thread relief in screw design.
Jaw Shape	Single Clamps: Concave shape of jaws to align to the spinous process bulbous top Double Clamps: Non-concave	Single Clamps: Non-concave Double Clamps: Non-concave
Teeth	Single Clamps: Small teeth on the upper (concave) part of jaws, same size teeth as predicate on lower part of jaws Double Clamps: Teeth all same size	Single Clamps: Teeth all same size Double Clamps: Teeth all same size
Distal End Shape	Single Clamps: Pointed jaw at distal end Double Clamps: Blunt jaw at distal end	Single Clamps: Blunt jaw at distal end Double Clamps: Blunt jaw at distal end
Clamping Range	Single Clamps: 11 mm Double Clamps: 9 mm	Single Clamps: 9 mm Double Clamps: 9 mm
Size Offerings	Short, Medium, and Tall	Short and Tall

XI. Discussion of the Performance Testing:

Testing conducted to demonstrate equivalency of the subject device to the predicate is summarized as follows:

Performance Testing Activity	Description
Functional Verification	Confirms that the Spinous Process Clamp design satisfies functional requirements.
Useful Life Testing	Confirms that the Spinous Process Clamps can operate normally throughout their useful life.

Navigation Accuracy Testing	Verifies the robustness and navigational accuracy of the Spinous Process Clamps.
Packaging Verification	Confirms that the Spinous Process Clamps when packaged in their packaging can withstand ship testing per ASTM D4169 and ISTA 2A.

Additionally, biological endpoint testing, conducted per recommendations from ISO 10993-1:2018, indicates that the subject devices are non-cytotoxic, non-sensitizing, non-irritating, non-toxic, and non-pyrogenic and pose a negligible risk of adverse biological effects to patients when used as intended.

XII. Conclusion:

The subject devices have shown through comparison to be substantially equivalent to the identified predicate.