June 5, 2025

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

Re: K242464
Trade/Device Name: Stealth™ Spine Clamps; ModuLeX™ Shank Mounts
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: June 2, 2025
Received: June 2, 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,

Shumaya Ali -S

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)*
K242464

Device Name
Stealth™ Spine Clamps
ModuLeX™ Shank Mounts

Indications for Use *(Describe)*

Stealth™ Spine Clamps

When used with Medtronic computer assisted surgery systems, defined as including the Stealth™ System, the following indications of use are applicable:

• The spine referencing devices are intended to provide rigid fixation between patient and patient reference frame for the duration of the surgery. The devices are intended to be reusable.

• The navigated instruments are specifically designed for use with Medtronic computer-assisted surgery systems, which are indicated for any medical condition in which the use of stereotactic surgery may be appropriate or vertebra can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.

• The Stealth™ spine clamps are indicated for skeletally mature patients.

ModuLeX™ Shank Mounts

When used with Medtronic computer assisted surgery systems, defined as including the Stealth™ System, the following indications of use are applicable:

• The spine referencing devices are intended to provide rigid fixation between patient and patient reference frame for the duration of the surgery. The devices are intended to be reusable.

• The navigated instruments are specifically designed for use with Medtronic computer assisted surgery systems, which are indicated for any medical condition in which the use of stereotactic surgery may be appropriate or vertebra can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.

• The ModuLeX™ shank mounts are indicated to be used with the CD Horizon™ ModuLeX™ Spinal System during surgery.

• The ModuLeX™ shank mounts are indicated for skeletally mature patients.

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

August 19, 2024

I. Company:

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Regulatory Affairs Director
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II. Proprietary Trade Name: Stealth™ Spine Clamps
ModuLeX™ Shank Mounts

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:

Subject Device	Predicate Device
Stealth™ Spine Clamps	StealthStation™ Spinous Process Clamps **K211442** S.E. July 8, 2021
ModuLeX™ Shank Mounts	Rod Clamps cleared as an accessory to the Navigated CAPSTONE® Trials, CLYDESDALE® Trials, and CAPSTONE® & CLYDESDALE® Inserter **K131425** S.E. August 14, 2013

VIII. Product Description:

The Stealth™ Spine Clamps are intended to provide rigid attachment between the patient and patient reference frame for the duration of the surgery. The subject devices are designed for use with the Stealth™ System and are intended to be reusable.

The ModuLeX™ Shank Mounts are intended to provide rigid attachment between the patient and patient reference frame for the duration of the surgery. The subject devices are designed for use with the Stealth™ System and are intended to be reusable.

IX. Indications for Use:

Stealth™ Spine Clamps

When used with Medtronic computer assisted surgery systems, defined as including the Stealth™ System, the following indications of use are applicable:

- The spine referencing devices are intended to provide rigid fixation between patient and patient reference frame for the duration of the surgery. The devices are intended to be reusable.
- The navigated instruments are specifically designed for use with Medtronic computer-assisted surgery systems, which are indicated for any medical condition in which the use of stereotactic surgery may be appropriate or vertebra can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.
- The Stealth™ spine clamps are indicated for skeletally mature patients.

ModuLeX™ Shank Mounts

When used with Medtronic computer assisted surgery systems, defined as including the Stealth™ System, the following indications of use are applicable:

- The spine referencing devices are intended to provide rigid fixation between patient and patient reference frame for the duration of the surgery. The devices are intended to be reusable.
- The navigated instruments are specifically designed for use with Medtronic computer assisted surgery systems, which are indicated for any medical condition in which the use of stereotactic surgery may be appropriate or vertebra can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.
- The ModuLeX™ shank mounts are indicated to be used with the CD Horizon™ ModuLeX™ Spinal System during surgery.
- The ModuLeX™ shank mounts are indicated for skeletally mature patients.

X. Comparison of the Technological Characteristics:

Stealth™ Spine Clamps

The subject Stealth™ Spine Clamps utilize the same fundamental scientific technology and have the same mode of operation and functionality as the predicate StealthStation™ Spinous Process Clamps (K211442). The subject devices have equivalent intended use and sterilization/reprocessing methods as the predicate. The changes in indications, configurations,

and materials from the predicate do not raise any new risks, or any concerns about safety and effectiveness.

Table 1. Technological Comparison of Subject Stealth™ Spine Clamps and Predicate StealthStation™ Spinous Process Clamps

Technological Characteristic	**Stealth™ Spine Clamps** (Subject)	**StealthStation™ Spinous Process Clamps** (Predicate, K211442)
Intended Use/Indications for Use	When used with Medtronic computer assisted surgery systems, defined as including the Stealth™ System, the following indications of use are applicable: • The spine referencing devices are intended to provide rigid fixation between patient and patient reference frame for the duration of the surgery. The devices are intended to be reusable. • The navigated instruments are specifically designed for use with Medtronic computer-assisted surgery systems, which are indicated for any medical condition in which the use of stereotactic surgery may be appropriate or vertebra can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy. • The Stealth™ spine clamps are indicated for skeletally mature patients.	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, 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.
Sterilization Method	Non-sterile, Steam sterilization, Reusable	Non-sterile, Steam sterilization, Reusable
Patient Fixation	Clamped to spinous process(es)	Clamped to spinous process(es)
Configurations	Straight – Short, Medium, Tall Double – Medium Angled – Short, Medium	Straight – Short, Medium, Tall Double – Short, Tall
Materials	• Titanium 6Al-4V • Titanium 6Al-4V with Type II Anondize • 300 Series Stainless Steel (SS) • 465 SS with Chrome Coat • Nitronic 60 with Chrome Coat	• Titanium 6Al-4V • 300 Series Stainless Steel (SS) • 17-4 SS with Chrome Coat

ModuLeX™ Shank Mounts

The subject ModuLeX ™ Shank Mounts utilize the same fundamental scientific technology and have similar functionality as the predicate Rod Clamps (K131425). The subject devices have equivalent and sterilization/reprocessing methods as the predicate (K131425). The changes in indications, design, and materials from the predicate do not raise any new risks, or any concerns about safety and effectiveness.

Table 2. Technological Comparison of Subject ModuLeX™ Shank Mounts and Predicate Rod Clamps

Technological Characteristic	**ModuLeX™ Shank Mounts** (Subject)	**Rod Clamps** (Predicate, K131425)
Indications for Use	When used with Medtronic computer assisted surgery systems, defined as including the	The spine referencing fixation devices are intended to provide rigid attachment

	Stealth™ System, the following indications of use are applicable: •The spine referencing devices are intended to provide rigid fixation between patient and patient reference frame for the duration of the surgery. The devices are intended to be reusable. •The navigated instruments are specifically designed for use with Medtronic computer assisted surgery systems, which are indicated for any medical condition in which the use of stereotactic surgery may be appropriate or vertebra can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy. •The ModuLeX™ shank mounts are indicated to be used with the CD Horizon™ ModuLeX™ Spinal System during surgery. •The ModuLeX™ shank mounts are indicated for skeletally mature patients.	between patient and patient reference frame for the duration of the surgery when used with a Medtronic computer-assisted surgery system. A Medtronic computer-assisted surgery system is defined as including StealthStation™ and/or Mazor™ systems. The devices are intended to be reusable. The navigated instruments are specifically designed for use with all Medtronic computer-assisted surgery systems, which are indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to 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
Patient Fixation	Attached to the CD Horizon™ ModuLeX™ implanted screw and stabilization pin driven into the patient's body anatomy	Attached to and implanted rod (not implant specific)
Materials	• Titanium 6Al-4V • 465 Stainless Steel (SS) • 465 SS Chrome Coat • 300 Series SS	• Titanium 6Al-4V • 17-4 Stainless Steel

XI. Discussion of the Performance Testing:

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

- Mechanical Robustness and Navigation Accuracy
- Functional Verification
- Useful Life Testing
- Packaging Verification
- Design Validation
- Summative Usability
- Biocompatibility

Additionally, biological endpoint testing, conducted per recommendations from ISO 10993-1 and the FDA Guidance Document on Use of ISO 10993-1 "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process", 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 Stealth™ Spine Clamps and ModuLeX™ Shank Mounts have shown through comparison to be substantially equivalent to the identified predicate.