



October 28, 2025

Tyber Medical, LLC
Chelsea Smith
Regulatory Affairs Manager
83 South Commerce Way
Suite 310
Bethlehem, Pennsylvania 18017

Re: K252742

Trade/Device Name: Navigated Instruments
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: August 28, 2025
Received: August 28, 2025

Dear Ms. Smith:

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K252742

?

Please provide the device trade name(s).

?

Navigated Instruments

Please provide your Indications for Use below.

?

The Navigated Instruments are intended to be used during preparation and placement of Medtronic Implants during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures.

The Navigated Instruments are specifically designed for use with the Medtronic 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 vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.

Please select the types of uses (select one or both, as applicable).

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

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510(k) #: K252742

510(k) Summary

Prepared on: 2025-10-23

Contact Details

[21 CFR 807.92\(a\)\(1\)](#)

Applicant Name	Tyber Medical, LLC
Applicant Address	83 South Commerce Way Suite 310 Bethlehem PA 18017 United States
Applicant Contact Telephone	267-671-7014
Applicant Contact	Mrs. Chelsea Smith
Applicant Contact Email	csmith@tybermed.com

Device Name

[21 CFR 807.92\(a\)\(2\)](#)

Device Trade Name	Navigated Instruments
Common Name	Stereotaxic instrument
Classification Name	Orthopedic Stereotaxic Instrument
Regulation Number	882.4560
Product Code(s)	OLO

Legally Marketed Predicate Devices

[21 CFR 807.92\(a\)\(3\)](#)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K221180	Anteralign™ Spinal System with Titan NanoLOCK Surface Technology Navigated Instruments	OLO
K192336	Navigated Anterolateral Disc Prep Instruments	OLO

Device Description Summary

[21 CFR 807.92\(a\)\(4\)](#)

The Navigated Instruments are spine preparation instruments made of surgical grade stainless steel per ASTM F899. These instruments are specifically designed for use in procedures where the use of stereotactic surgery may be appropriate. When used with the appropriate Medtronic single-use sterile spheres the subject devices can be used as navigated surgical instruments with the Medtronic StealthStation™ System (Medtronic computer-assisted surgery system) to track the instruments in the surgical field.

Specialized cases and trays are available for optional use with the Navigated Instruments. They are manufactured from stainless steel per ASTM F899, aluminum per ASTM B209, and silicone. Ancillary non-navigated instrumentation is available for optional use with the Navigated Instruments. These instruments are not specifically intended to be used with the subject device.

The Navigated Instruments are provided non-sterile.

Intended Use/Indications for Use

[21 CFR 807.92\(a\)\(5\)](#)

The Navigated Instruments are intended to be used during preparation and placement of Medtronic Implants during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures.

The Navigated Instruments are specifically designed for use with the Medtronic 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 vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.

Indications for Use Comparison

[21 CFR 807.92\(a\)\(5\)](#)

The subject device indications for use/intended use are substantially equivalent to those of the predicate device.

Technological Comparison

[21 CFR 807.92\(a\)\(6\)](#)

The subject navigated instruments are made of the same materials, have substantially equivalent indications for use/intended use, utilize the same principles of operation, and are similar in design to the predicate devices cleared under K221180 and K192336.

Non-Clinical and/or Clinical Tests Summary & Conclusions

[21 CFR 807.92\(b\)](#)

Non-Clinical Testing:

Evaluations and testing was completed to ensure the functionality and compatibility with the Medtronic StealthStation™ System. The following was completed:

- Navigation Accuracy Analysis
- Simulated Use Validation
- Biocompatibility Evaluation per ISO 10993-1:2018

Clinical Testing:

Not applicable.

Conclusions:

Based on the information contained in this submission, the Navigated Instruments are substantially equivalent to the predicate device.