



May 29, 2026

Priscila Saraiva
Senior Regulatory Affairs Specialist
83 S. Commerce Way
Suite 310
Bethlehem, Pennsylvania 18017

Re: K261060

Trade/Device Name: Navigated LLIF Impactable Tracker
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: March 31, 2026
Received: March 31, 2026

Dear Priscila Saraiva:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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

510(k) Number (if known)

K261060

Device Name

Navigated LLIF Impactable Tracker

Indications for Use (Describe)

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.

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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K261060

510(k) Summary

Device Trade Name: Navigated LLIF Impactable Tracker

Applicant Name: Tyber Medical, LLC

Contact: Ms. Priscila Saraiva

Date Prepared: May 26, 2026

Common Name: Stereotaxic instrument

Classification Name: Orthopedic Stereotaxic Instrument

Product Code: OLO

Predicate Device: K252742 Navigated Instruments

Device Description: 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 Stealth™ Systems (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 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.

Indications for Use: 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.

Substantial Equivalence: The subject device indications for use/intended use are the same the predicate device.

Performance Testing: The subject Navigated LLIF Impactable Tracker is made of the same materials, have the same intended use, utilize the same principles of operation, and are similar in design to the predicate devices cleared under K252742 and K124004.

Simulation testing was conducted with surgeons using cadaveric specimens to evaluate the performance and usability of the Navigation Tracker under simulated clinical conditions. The test demonstrated that the Navigation Tracker performed as intended and supported successful completion of the intended surgical workflow. All predefined acceptance criteria were met during the evaluation, confirming the device's ability to function safely and effectively for its intended use.

Conclusion: Based on the information contained in this submission, the Navigated LLIF Impactable Tracker is substantially equivalent to the predicate device.