



April 16, 2026

Foundation Surgical Group, Inc.  
% Hannah Taggart, MS, RAC  
Engineer & Regulatory Specialist  
Applied Technical Services (Empirical Technologies)  
4628 Northpark Drive  
Colorado Springs, Colorado 80918

Re: K260011

Trade/Device Name: Foundation Surgical Navigated Lateral Disc Prep Instruments  
Regulation Number: 21 CFR 882.4560  
Regulation Name: Stereotaxic Instrument  
Regulatory Class: Class II  
Product Code: OLO  
Dated: January 2, 2026  
Received: March 18, 2026

Dear Ms. Taggart:

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](mailto: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.

K260011

?

Please provide the device trade name(s).

?

Foundation Surgical Navigated Lateral Disc Prep Instruments

Please provide your Indications for Use below.

?

Foundation Surgical Navigated Lateral Disc Prep Instruments are intended to be used during preparation of the intervertebral disc space during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures.

Foundation Surgical Navigated Lateral Disc Prep Instruments are specifically designed for use with the Medtronic StealthStation™ S8 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. An instrument may incorporate a measuring function, which has uses as described on the label and the instruments.

The Navigated Trials are intended to be used to facilitate implant size selection of matching implants during spinal surgery.

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)

?

Submitter's Name:	Foundation Surgical Group, Inc.
Submitter's Address:	7327 E Tierra Buena Lane Scottsdale, Arizona 85260
Submitter's Telephone:	1-727-209-7436
Contact Person:	Hannah Taggart, MS, RAC Applied Technical Services (Empirical Technologies) 1-719-457-1152 <a href="mailto:htaggart@atslab.com">htaggart@atslab.com</a>
Date Summary was Prepared:	April 10, 2026
Trade or Proprietary Name:	Foundation Surgical Navigated Lateral Disc Prep Instruments
Device Classification Name:	Orthopedic Stereotaxic Instrument
Classification & Regulation #:	Class II per 21 CFR §882.4560
Product Code:	OLO
Classification Panel:	Orthopedic – Restorative, Repair and Trauma Devices (DHT6C)

#### DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Foundation Surgical Navigated Lateral Disc Prep Instruments are orthopedic stereotaxic instruments designed for use in procedures where the use of stereotactic surgery may be appropriate. The instruments are compatible with Medtronic NavLock Trackers and Medtronic single-use sterile spheres to allow computer-assisted surgery with the StealthStation S8 system to track the instruments in the surgical field. The Foundation Surgical Navigated Lateral Disc Prep Instruments are manufactured from medical grade stainless steel per ASTM F899 and include trials, dilators, awls, taps, shavers, cobbs, and osteotomes for disc preparation for the placement of the Interwedge® Lateral Interbody Fusion (LIF) system into the treated disc space.

#### INDICATIONS FOR USE

Foundation Surgical Navigated Lateral Disc Prep Instruments are intended to be used during preparation of the intervertebral disc space during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures.

Foundation Surgical Navigated Lateral Disc Prep Instruments are specifically designed for use with the Medtronic StealthStation™ S8 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. An instrument may incorporate a measuring function, which has uses as described on the label and the instruments.

The Navigated Trials are intended to be used to facilitate implant size selection of matching implants during spinal surgery.

#### TECHNOLOGICAL CHARACTERISTICS

The subject and predicate devices have nearly identical technological characteristics and the minor differences do not raise any new issues of the safety and effectiveness. Specifically, the following characteristics are similar between the subject and predicates:

- Device design and critical geometry
- Indications for use

- Materials of manufacture
- Principles of operation and function

**Predicate Devices**

510k #	Trade or Proprietary or Model Name	Manufacturer	Product Code	Predicate Type
K211441	Navigated Anterolateral Disc Prep Instruments	Medtronic Sofamore Danek USA, Inc.	OLO	Primary
K131425	Navigated CLYDESDALE Trials	Medtronic Navigation, Inc.	OLO	Additional
K223494	Navigated Reusable Instruments for use with StealthStation™	Medtronic Sofamor Danek, USA Inc	OLO	Additional

The Medtronic navigated instruments are intended for use in the surgical preparation and implantation of Medtronic implants while the subject instruments are intended for the surgical preparation for implantation of Foundation Surgical implants. This difference does not affect the safety and efficacy of the subject device since each subject instrument has an equivalent Medtronic counterpart of the same critical geometry already programmed into the StealthStation software.

There are no differences between the subject and predicate devices which raise questions for the safety and efficacy of the subject devices.

**PERFORMANCE DATA**

The Foundation Surgical Navigated Lateral Disc Prep Instruments have been evaluated through an engineering analysis and geometric comparison to predicate devices to establish substantial equivalence. The results of this engineering analysis show that the subject devices are substantially equivalent to the cleared predicate.

**CONCLUSION**

The overall technological characteristics and engineering analysis lead to the conclusion that the Foundation Surgical Navigated Lateral Disc Prep Instruments are substantially equivalent to the predicate device.