



December 4, 2025

Spineology Inc.
Megan Polos
Senior Regulatory Affairs Specialist
7800 3rd Street North
Suite 600
Saint Paul, Minnesota 55128

Re: K251943

Trade/Device Name: OptiMesh Navigation Instruments for Portal Placement
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: June 24, 2025
Received: June 24, 2025

Dear Megan Polos:

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.

K251943

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Please provide the device trade name(s).

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Spineology Navigation Instruments

Please provide your Indications for Use below.

?

Spineology Navigation Instruments are indicated for use during the preparation and placement of:

- Spineology's Fortress, Threshold, Threshold V2, and Palisade pedicle screws
- Spineology's OptiMesh® Portal Assembly

during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open, minimally invasive, or percutaneous orthopedic procedures.

These instruments are designed for use with the Medtronic StealthStation® Spine 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 the spine or pelvis, can be identified relative to images 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) Summary

Date Prepared: December 2, 2025

Submitter: Spineology Inc.
7800 3rd Street North
Suite 600
Saint Paul, MN 55128
Establishment Registration Number: 2135156

Contact Person: Megan Polos
Senior Regulatory Affairs Specialist
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Email: mpolos@spineology.com

Device Name and Classification

Trade Name: Spineology Navigation Instruments
Classification Name: Stereotaxic Instrument
Product Codes: OLO
Regulatory Class: Class II
Regulation Number: 21 CFR 882.4560
Panel: Orthopedic

Predicate Devices

Primary:	K213876	Spineology Navigation Instruments
Reference:	K170011	StealthStation S8 Spine Software v1.0.0

1. Purpose

The purpose of this premarket notification is to obtain FDA clearance for use of Medtronic's NavLock® Tracker array with the OptiMesh® Navigation Instruments for Portal Placement, specifically for placement of the dilator.

2. Device Description

Spineology Navigation Instruments are non-sterile, reusable surgical instruments that are manufactured from stainless steel and operated manually.

Spineology Navigation Instruments for Pedicular Fixation include Awls, Bone Taps, Drills, and Screwdrivers. The navigable instruments are equipped with a dimensional feature that allows connection to Medtronic's NavLock Trackers. A Navigation Adapter is also available with dimensional features that allows the same instruments to connect to Medtronic's SureTrak™ II Universal Trackers. These instruments are compatible with Spineology's Fortress™, Threshold™, Threshold™ V2, and Palisade™ Pedicular Fixation Systems and Medtronic's StealthStation® S7 (v2.1.0) and S8 (v1.0.0) Spine System.

Spineology Navigation Instruments for Portal Placement include a Dilator, Portal, Tightener, Wrench, and a Portal Surrogate. The navigable instruments are equipped with dimensional features that allow connection to Medtronic's SureTrak II Universal Trackers. These instruments are compatible with Spineology's OptiMesh Expandable Interbody Fusion System for Access Portal Placement and Medtronic's StealthStation® S8 (v1.2.0) Spine System. The navigable Dilator instrument is also equipped with a dimensional feature that allows connection to Medtronic's NavLock Tracker arrays.

Spineology Navigation Instruments are intended to be used during the preparation and placement of spinal implants in optically navigated procedures

3. Indications for Use

Spineology Navigation Instruments are indicated for use during the preparation and placement of:

- Spineology's Fortress™, Threshold™, Threshold™ V2, and Palisade™ pedicle screws
- Spineology's OptiMesh® Portal Assembly

during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open, minimally invasive, or percutaneous orthopedic procedures.

These instruments are designed for use with the Medtronic StealthStation® Spine 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 the spine or pelvis, can be identified relative to images of the anatomy.

4. Technological Characteristics

When compared to the predicate device, the OptiMesh Navigation Instruments for Portal Placement, specifically placement of the Dilator, have the same intended use and a majority of the same technological characteristics, including:

- | | |
|-------------------------------------|--|
| • Primary Design Features | • Device Design |
| • Materials of Construction | • Risk Profile |
| • Function / Performance | • Use with Spineology's Instrument Systems |
| • Fundamental Scientific Technology | • Use with Medtronic's StealthStation System |
| • Principle of Operation | |

Different technological characteristics exist, including:

- Navigation System Tracker Compatibility

The subject OptiMesh Navigation Instruments for Portal Placement, specifically the Dilator is identical in technological characteristics to the predicate device with the exception of the Navigation System Tracker Compatibility. The addition of the Medtronic NavLock Tracker to the system compatibility of the subject Navigation Dilator instrument is supported by the technological characteristics comparison to the Spineology Navigation Instruments for pedicular

fixation predicate device, particularly that the differences in technological characteristics do not raise difference questions of safety and effectiveness.

5. Non-Clinical Performance Testing

Design verification testing, including mating, registration, and accuracy, was conducted to ensure that OptiMesh Navigation Instruments for Portal Placement, specifically placement of the dilator, is safe and effective for their intended use, to ensure functionality and compatibility with the Medtronic StealthStation S8 Spine System, and to demonstrate substantial equivalence to the predicate device.

- Instrument mating testing was performed to ensure that OptiMesh Navigation Instruments for Portal Placement, specifically the dilator, can be mated with the Medtronic NavLock Tracker to allow for instrument registration and optical navigation.
- Registration testing was performed to ensure that OptiMesh Navigation Instruments for Portal Placement, specifically the dilator, can be registered with the Medtronic StealthStation S8 Spine System to allow for optical navigation.
- Accuracy testing was performed to ensure that OptiMesh Navigation Instruments for Portal Placement, specifically the dilator, can be optically navigated accurately, as compared to predicate instruments, under expected-use conditions in a simulated environment with the Medtronic StealthStation S8 Spine System.
- The Spineology Navigation Instruments have been evaluated through an engineering analysis and geometric comparison to predicate devices to establish the safety and efficacy for accuracy performance.
- The biocompatibility evaluation leveraged equivalence in materials and manufacturing processes to previously cleared devices (K213876) and identical processes to currently manufactured devices. The results of these evaluations show that the subject is substantially equivalent to the cleared predicate.

6. Clinical Performance Testing

Clinical performance testing was not necessary to support the subject OptiMesh Navigation Instruments for Portal Placement.

7. Conclusion

Based on the intended use, technological characteristics, and comparison to the predicate device, the subject OptiMesh Navigation Instruments for Portal Placement have been shown to be substantially equivalent to the legally marketed predicate device.