August 5, 2022

Spineology Inc.
Andrew Adams
Group Director of Regulatory & Quality Affairs
7800 3rd Street North, Suite 600
Saint Paul, Minnesota 55128

Re: K213876
Trade/Device Name: Spineology Navigation Instruments
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: June 24, 2022
Received: June 27, 2022

Dear Andrew Adams:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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, 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)*
K213876

Device Name
Spineology Navigation Instruments

Indications for Use *(Describe)*

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.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Spineology

510(k) Summary

Date Prepared: August 5, 2022

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

Contact Person: Andrew Adams
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Device Name and Classification

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

Predicate Device		
Primary:	K182345	Spineology Navigation Instruments
Reference:	K170011	Medtronic StealthStation™ S8 Spine Software v1.0.0
Reference:	DEN200010	OptiMesh® Expandable Interbody Fusion System

1. Purpose

The purpose of this premarket notification is to obtain FDA clearance for the introduction of new instruments to the Spineology Navigation Instruments family. These subject instruments are for Portal Placement navigation, specifically Spineology's OptiMesh Portal Assembly.

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.

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, Spineology Navigation Instruments for Portal Placement have the same intended use and the same technological characteristics, including:

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

5. Non-Clinical Testing

Design verification testing, including mating, registration, and accuracy, was conducted to ensure that Spineology Navigation Instruments for Portal Placement are 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 Spineology Navigation Instruments for Portal Placement can be mated with the Medtronic SureTrak II Universal Tracker to allow for instrument registration and optical navigation. The ability to withstand expected-use conditions was also confirmed.

- Registration testing was performed to ensure that Spineology Navigation Instruments for Portal Placement can be registered with the Medtronic StealthStation S8 Spine System to allow for optical navigation.

- Accuracy testing was performed to ensure that Spineology Navigation Instruments for Portal Placement 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.

6. Conclusion

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