May 2, 2018

Spineology Inc.
% Jacqueline Hauge
Regulatory Affairs Manager
Spineology, Inc.
7800 3rd Street North, Suite 600
St. Paul, Minnesota 55128

Re: K180796
Trade/Device Name: Spineology Navigation Instruments
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: March 26, 2018
Received: March 27, 2018

Dear Jacqueline Hauge:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K180796

Device Name
Spineology Navigation Instruments

Indications for Use *(Describe)*

Spineology Navigation Instruments are intended to be used during the preparation and placement of Spineology's Fortress, Threshold, Threshold V2, and Palisade pedicle screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. These instruments are 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 skull, long bone, or vertebra, can be identified relative to a CT- or MR-based model, fluoroscopic images, or digitalized 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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Date Prepared: March 26, 2018

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

Establishment Registration Number: 2135156

Contact Person: Jacqueline A. Hauge
Regulatory Affairs Manager

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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

K172518 Spineology Navigation Instruments (Spineology Inc.)

1. Purpose

The purpose of this Premarket Notification is to obtain FDA clearance for the addition of Spineology Navigation Instruments to Spineology's FDA cleared Navigation Instrument set.

2. Device Description

A. Spineology Navigation Instruments

Spineology Navigation Instruments are non-sterile, reusable instruments; including awls, bone taps, drills, and screwdrivers that are operated manually. These instruments are manufactured from stainless steel in accordance with ASTM F899 and are intended to be used within the context and limitations of the indications for use for Spineology's FDA-cleared Fortress™, Threshold™, Threshold™ V2, and Palisade™ Pedicular Fixation Systems and the Medtronic Synergy Experience StealthStation® System S7 (v2.1.0).

B. Spineology Pedicular Fixation Systems

Spineology Fortress, Threshold, Threshold V2, and Palisade Pedicular Fixation Systems consist of screws, curved and straight rods, and ConneX Connector devices to allow the surgeon to build an implant system to fit the patient's anatomical and physiological requirements. All screws are available with or without a hydroxyapatite coating. These systems are intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine. The screws can be placed in the pedicles in a variety of trajectories ranging from the standard anatomic transpedicular path projected medially toward the ventral vertebral body, to a caudocephalad path sagittally and a laterally directed path in the transverse plane.

3. Indications for Use

Spineology Navigation Instruments are intended to be used during the preparation and placement of Spineology's Fortress, Threshold, Threshold V2, and Palisade pedicle screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. These instruments are 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 skull, long bone, or vertebra, can be identified relative to a CT- or MR-based model, fluoroscopic images, or digitalized landmarks of the anatomy.

4. Technological Characteristics

When compared to the predicate device, Spineology Navigation Instruments have the same intended use and equivalent technological characteristics, including:

- Primary Design Features, including but not limited to, critical dimensions, distal (functional) end features (i.e., implant/inserter interface), and proximal end mating features (i.e., Medtronic NavLock Tracker Array interface)
- Materials of Construction
- Function/Performance
- Principle of Operation
- Fundamental Scientific Technology
- Use with Medtronic StealthStation System

5. Non-Clinical Testing

Spineology performed design verification activities to demonstrate that the design outputs of the subject Spineology Navigation Instruments met the design input requirements. Due to the substantial equivalence of the primary technological characteristics of the subject Spineology Navigation Instruments as compared to the predicate device, existing verification and validation testing previously provided to FDA was used to support the safety and effectiveness of the subject devices. Previously conducted testing included, but was not limited to, the following:

- Instrument mating testing which evaluated the connection between the Medtronic NavLock Tracker Array and Spineology Navigation Instruments.
- Registration testing which ensured that Spineology Navigation Instruments can be registered to the Medtronic StealthStation System.

- Accuracy testing which included side-by-side comparison of Spineology Navigation Instruments to equivalent Medtronic Navigation Instruments intended for use with the Medtronic StealthStation System.

In addition to design verification, Spineology conducted a risk assessment to confirm that the subject Spineology Navigation Instruments do not introduce new issues of safety or effectiveness.

6. Clinical Testing

Clinical testing was not performed or required to establish the substantial equivalence of Spineology Navigation Instruments to the predicate device.

7. Conclusion

Spineology has demonstrated the substantial equivalence of the subject Spineology Navigation Instruments through the comparison of these devices to the legally marketed predicate device and confirmed that the intended use is the same and any difference in technological characteristics between the subject and predicate device do not raise new issues of safety and effectiveness.