DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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August 21, 2017

Spineology Inc.
Ms. Jacqueline A. Hauge
Regulatory Affairs Manager
7800 3rd Street North, Suite 600
Saint Paul, Minnesota 55128

Re: K172107
Trade/Device Name: Threshold™ V2 Pedicular Fixation System,
Threshold™ Pedicular Fixation System,
Fortress™ Pedicular Fixation System,
Palisade™ Pedicular Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: NKB
Dated: July 19, 2017
Received: July 20, 2017

Dear Ms. 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Katherine D. Kavlock
-S

for
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K172107

Device Name
Threshold™ V2 Pedicular Fixation System, Threshold™ Pedicular Fixation System, Fortress™ Pedicular Fixation System, Palisade™ Pedicular Fixation System

Indications for Use *(Describe)*
Spineology Pedicular Fixation Systems are intended for posterior, non-cervical fixation as an adjunct to fusion in skeletally mature patients for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies) spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis and/or lordosis); tumor; pseudoarthrosis; and/or failed previous fusion.

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.

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Spineology

510(k) Summary

Date Prepared: August 16, 2017

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 Names: Threshold™ V2 Pedicular Fixation System,
Threshold™ Pedicular Fixation System,
Fortress™ Pedicular Fixation System,
Palisade™ Pedicular Fixation System

Common Name: Thoracolumbosacral Pedicle Screw System

Classification Name: Orthosis, Spinal Pedicle Fixation

Product Codes: NKB

Regulatory Class: Class II

Regulation Number: 21 CFR 888.3070

Panel: Orthopedic

Predicate Devices

Primary:	K170255	Threshold™ V2 Pedicular Fixation System (Spineology Inc.)
Additional:	K170251	Threshold™ Pedicular Fixation System (Spineology Inc.)
	K170268	Fortress ™ Pedicular Fixation System (Spineology Inc.)
	K171438	Palisade™ Pedicular Fixation System (Spineology Inc.)
	K120838	Synthes Matrix™ System (Synthes Spine)
	K111478	Power Adapter Instrument Accessory (Stryker Spine)

A. Description of Device Modifications

The purpose of this submission is to obtain FDA clearance for the following modifications to Spineology's Fortress, Threshold, Threshold V2, and Palisade Pedicular Fixation Systems:

Addition to System	Fortress	Threshold	Threshold V2	Palisade
4.75mm cobalt chrome rods (25mm to 400mm)		x	x	
5.5mm titanium rods (600mm)		x	x	
4.5mm pedicle screws and reduction screws (25 - 50mm lengths)			x	
7.5mm pedicle screws and reduction screws (70 – 100mm lengths)			x	
Power Adapter	x	x	x	x

This 510(k) also supports a labeling update to include reference to the added implantable devices and the option for pedicle screw preparation and placement using powered instrumentation.

B. Device Description

Pedicular Fixation Systems

Spineology Fortress™, Threshold™, Threshold™ V2, and Palisade™ Pedicular Fixation Systems consist of screws (titanium alloy), curved and straight rods (see table below for diameters and material), and ConneX™ Connector (see table below for configurations and materials) 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.

ConneX™ Cross Connector

Spineology ConneX Cross Connector devices are transversely-placed titanium alloy implants that are intended to connect the rod on one side of a spinal construct to the rod on the other side. These devices are manufactured from titanium alloy and are adjustable to allow the surgeon to build an implant system to fit the patient's anatomical and physiological requirements. ConneX Cross Connector devices 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.

ConneX™ Rod Connector

Spineology ConneX Rod Connector devices are titanium alloy implants that are intended to connect two rods in a spinal construct. These devices are manufactured from titanium alloy and the components allow the surgeon to build an implant system to fit the patient's anatomical and physiological requirements. ConneX Rod Connector devices 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.

Component	Fortress	Threshold	Threshold V2	Palisade
5.5mm Curved Rod (titanium alloy)		x	x	
5.5mm Straight Rod (titanium alloy)		x	x	
4.75mm Curved Rod (cobalt chrome)	x	x	x	x
4.75mm Straight Rod (cobalt chrome)	x	x	x	x
ConneX Cross Connectors (titanium alloy)	x	x	x	x
ConneX Rod Connector, Off-set (titanium alloy)	x	x	x	x
ConneX Rod Connector, Axial (titanium alloy)		x	x	
ConneX Rod Connector, Parallel (titanium alloy)		x	x	

Power Adapter

The Spineology Power Adapter is an instrument accessory intended to facilitate the preparation and placement of pedicle screws using powered instrumentation as an optional alternative to the existing manual technique. The Power Adapter is intended for exclusive use with Spineology Fortress, Threshold, Threshold V2, and Palisade System surgical instruments. The Power Adapter serves as a mechanical interface between the power driver and surgical instruments. When the Power Adapter is attached, the power driver provides appropriate power to rotate the surgical instrument for preparation and placement of pedicle screws.

C. Indications for Use

Spineology Pedicular Fixation Systems are intended for posterior, non-cervical fixation as an adjunct to fusion in skeletally mature patients for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies) spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis and/or lordosis); tumor; pseudoarthrosis; and/or failed previous fusion.

D. Comparison to Predicate

When compared to the predicate device, the subject implantable devices and Power Adapter instrument accessory have the same:

- Intended Use
- Indications for Use
- Fundamental Scientific Technology
- Principle of Operation
- Materials of Construction

E. Non-Clinical Testing

4.75mm and 5.5mm Rods

Assessments, verifications, and product adoptions included:

- Drawing verification
- Confirmatory ASTM F1798 Grip Testing
- Packaging adoption
- Sterilization adoption
- Risk Assessment
- Shelf Life adoption
- Confirmatory ASTM F1717 (dynamic compression bending)

4.5mm Pedicle and Reduction Screws

A thorough review, risk assessment, and comparison of these devices to equivalent devices currently cleared by FDA for use in other Spineology Pedicle Screw Systems confirmed that the 4.5mm Threshold V2 pedicle and reduction screws for their intended use are substantially equivalent to the predicate devices, and do not introduce any known new risks based the equivalence of their primary design characteristics, materials, manufacturing processes, existing mechanical performance testing, and product experience as compared to the predicate device.

7.5mm Pedicle and Reduction Screws (Additional Lengths)

A thorough review, risk assessment, and comparison of these devices to equivalent devices currently cleared by FDA for use it its other Pedicle Screw Systems confirmed that the 7.5mm Threshold V2 pedicle and reduction screws for their intended use are substantially equivalent to the predicate devices, and do not introduce any known new risks based the equivalence of their primary design characteristics, materials, manufacturing processes, existing mechanical performance testing, and product experience as compared to the predicate device.

Power Adapter

The following non-clinical testing was conducted for the Power Adapter device:

- Strength assessment testing of instrumentation and implantable devices under simulated clinical use conditions
- Screw loading and screw insertion during normal use without loss of function
- Compatibility with existing surgical instruments
- Evaluation of quality and accuracy of screw placement in simulated use environment

F. Conclusion

Based on the indications for use, technological characteristics, and comparison to the predicate devices, Spineology has demonstrated that the subject device components are substantially equivalent to the legally marketed predicate devices for their intended use.