DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 14, 2017

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

Re: K170251
Trade/Device Name: Threshold™ Pedicular Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: NKB
Dated: January 26, 2017
Received: January 27, 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 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 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,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170251

Device Name
Threshold™ Pedicular Fixation System

Indications for Use *(Describe)*
The Spineology Threshold™ Pedicular Fixation System is 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: April 11, 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 Name:	Threshold™ 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:	K161694	Threshold™ Pedicular Fixation Systems (Spineology Inc.)
Additional:	K143403	Threshold™ Pedicular Fixation System (Spineology Inc.)
	K160980	Threshold™ and Palisade™ Pedicular Fixation Systems (Spineology Inc.)
	K123352	S4™ Spinal System (Aesculap Implant Systems, Inc.)
	K152968	Arsenal™ Spinal Fixation System (Alphatec Spine, Inc.)
	K120838	Synthes Matrix™ System (Synthes Spine)

I. Purpose

The purpose of this submission is to obtain FDA clearance for the addition of Spineology's ConneX™ Cross Connector, ConneX™ Rod Connector, and 5.5 titanium Straight Rod devices to its Threshold™ Pedicular Fixation System.

II. Regulatory History

Device Name	510(k) #	Purpose of 510(k)
Threshold™ Pedicular Fixation System	K143403	Initial FDA Clearance
	K160980	Addition of Hydroxyapatite (HA) coated pedicle screws
	K161694	Addition of solid core pedicle screws

III. Device Description

A. Threshold™ System

The Spineology Threshold Pedicular Fixation System consists of cannulated screws (titanium alloy), curved and straight rods (titanium alloy), and adjustable ConneX Cross Connector (titanium alloy), and fixed ConneX Rod Connector (titanium alloy) devices to allow the surgeon to build an implant system to fit the patient's anatomical and physiological requirements. Threshold cannulated screws are available with or without a hydroxyapatite coating. The system is 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 cannulated 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.

B. ConneX™ Cross Connectors

Spineology ConneX Cross Connector devices are transversely-placed implants that are intended to connect the rod on one side of the 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 be used with Spineology's Fortress™, Threshold™, Threshold V2™, and Palisade™ Pedicular Fixation Systems which 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.

C. ConneX™ Rod Connectors

Spineology ConneX Rod Connector devices are 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 be used with Spineology's Fortress™, Threshold™, Threshold™ V2, and Palisade™ Pedicular Fixation Systems which 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.

IV. Indications for Use

The Spineology Threshold™ Pedicular Fixation System is 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.

V. Comparison to Predicate

When compared to the predicate devices, the ConneX Cross Connector, ConneX Rod Connector, and Straight Rod devices have the same:

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

VI. Non-Clinical Testing

A. ConneX™ Cross Connectors and ConneX™ Rod Connectors

The following mechanical testing was conducted on representative worst case ConneX Cross Connector and ConneX Rod Connector devices in accordance with FDA Guidance: Spinal System 510(k)s (2004) and applicable American Society for Testing and Materials (ASTM) standards:

ASTM F1717
- Static Compression Bending
- Dynamic Compression Bending

ASTM F1798
- Flexural Grip

ASTM F2193
- Static Cantilever Bending

Bacterial endotoxin testing (BET) was conducted in accordance with ANSI/AAMI ST-72:2011.

B. Straight Rods

The following mechanical testing was conducted on representative Straight Rod devices in accordance with FDA Guidance: Spinal System 510(k)s (2004) and applicable American Society for Testing and Materials (ASTM) standards:

ASTM F1717-15
- Static Compression Bending

Bacterial endotoxin testing (BET) was conducted in accordance with ANSI/AAMI ST-72:2011.

VII. Conclusion

Based on the indications for use, technological characteristics, and comparison to the predicate devices, the ConneX Cross Connector, ConneX Rod Connector, and Straight Rod devices have been shown to be substantially equivalent to the legally marketed predicate devices.