



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center – WO66-G609  
Silver Spring, MD 20993-0002

Spineology Incorporated  
Ms. Jacqueline Hauge  
Regulatory Affairs Manager  
7800 3<sup>rd</sup> Street North, Suite 600  
Saint Paul, Minnesota 55128-5455

August 25, 2016

Re: K161694

Trade/Device Name: Threshold™ Pedicular Fixation System

Regulation Number: 21 CFR 888.3070

Regulation Name: Pedicle screw spinal system

Regulatory Class: Class III

Product Code: NKB, MNH, MNI

Dated: June 17, 2016

Received: June 20, 2016

Dear Ms. Hauge:

This letter corrects our substantially equivalent letter of July 15, 2016.

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 Part 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" (21CFR 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

## Indications for Use

510(k) Number (if known)

K161694

Device Name

Threshold™ Pedicular Fixation System

Indications for Use (Describe)

The 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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**Date Prepared:** July 8, 2016

**Submitter:** Spineology Inc.  
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**Device Name and Classification**

**Trade Name:** Threshold™ Pedicular Fixation System  
**Common Name:** Pedicle Screw System  
**Classification Name:** Orthosis, Spinal Pedicle Fixation  
**Product Codes:** NKB, MNI, MNH  
**Regulatory Class:** NKB: Class III | MNI, MNH: Class II  
**Regulation Number:** NKB: 888.3070(b)(2) | MNI, MNH: 888.3070(b)(1)  
**Panel:** Orthopedic

**Predicate Devices**

<b>Primary:</b>	K143403	Threshold™ Pedicular Fixation System
<b>Additional:</b>	K140010	Fortress™ Pedicle Screw System
	K160980	Threshold™ Pedicular Fixation System
	K152148	Fortress™ Pedicle Screw System

**Purpose**

Obtain 510(k) clearance for the addition of uncoated and hydroxyapatite (HA) coated Threshold solid pedicle screws to Spineology's Threshold Pedicular Fixation System.

**Device Description**

Spineology's Threshold Pedicular Fixation System consists of cannulated and solid titanium alloy screws and rods to allow the surgeon to build an implant system to fit the patient's anatomical and physiological requirements. Threshold cannulated and solid 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 and solid screws can be placed in the pedicles in a variety of trajectories ranging from 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.

### **Indications for Use**

The 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.

### **Comparison to Predicate**

When compared to the predicate devices, uncoated and HA-coated Threshold solid pedicle screws have the same:

- Intended Use
- Indications for Use
- Fundamental Scientific Technology
- Principle of Operation
- Biological Safety
- Biological Safety
- Base Materials
- Size Offering
- Hydroxyapatite (HA) Coating

### **Non-Clinical Testing**

Testing was not required to support the addition of uncoated and HA-coated Threshold solid pedicle screws. Spineology's risk analysis, a finite element analysis (FEA), and previous mechanical testing conducted on the predicate devices is sufficient to demonstrate the substantial equivalence of the uncoated and HA-coated Threshold solid pedicle screws to the predicate devices.

The previous mechanical testing was performed in accordance with:

- ASTM F1798-97 Standard Guide for Evaluating Static and Fatigue Properties of Interconnection Mechanisms and Subassemblies Used in Spinal Arthrodesis Implants
- ASTM F543-13 Standard Specification and Test Methods for Metallic Medical bone Screws
- ASTM F1717-13 Standard Specification and Test Methods for Spinal Implant Constructs in a Vertebrectomy Model

Bacterial Endotoxin testing (BET), also known as the Limulus amoebocyte lysate (LAL) test, was performed per ANSI/AAMI/ST72 to a limit of <20 EU/Device.

### **Conclusion**

Spineology has demonstrated that the uncoated and HA-coated Threshold solid pedicle screws are substantially equivalent to the predicate devices. The fundamental scientific principle, primary technological characteristics, and intended use are unchanged from the predicate devices.