



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

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

May 26, 2016

Re: K160980

Trade/Device Name: Threshold Pedicular Fixation System, Palisade Pedicular Fixation System

Regulation Number: 21 CFR 888.3070

Regulation Name: Pedicle screw spinal system

Regulatory Class: Class III

Product Code: NKB, MNI, MNH

Dated: April 5, 2016

Received: April 7, 2016

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 Parts 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" (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 yours,

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)

K160980

Device Name

Threshold Pedicular Fixation System

Palisade Pedicular Fixation System

Indications for Use (Describe)

The Threshold Pedicular Fixation System and Palisade Pedicular Fixation System 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.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"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."

510(k) Summary

Date Prepared: April 05, 2016

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

Contact Person: Jacqueline A. Hauge
Regulatory Affairs Manger
Phone: 651.256.8534
Fax: 651.256.8505
Email: jhauge@spineology.com

Device Name and Classification

Trade Name: Threshold Pedicular Fixation System
Palisade Pedicular Fixation System

Common Name: Pedicle Screw System

Classification Name: Pedicle Screw Spinal System

Product Codes: NKB,MNI, MNH

Regulatory Class: MNI, MNH: Class II | NKB: Class III

Regulation Number: MNI, MNH: 888.3070(b)(1) | NKB: 888.3070(b)(2)

Panel: Orthopedic

Predicate Devices

Primary: K152148 Fortress Pedicle Screw System

Additional: K143403 Threshold Pedicular Fixation System
K153323 Palisade Pedicular Fixation System

Purpose

Obtain 510(k) clearance for the addition of hydroxyapatite (HA) coating to Spineology's Threshold and Palisade pedicle screws.

Device Description - Threshold Pedicular Fixation System

The Spineology Threshold Pedicular Fixation System consists of titanium alloy screws and rods to allow the surgeon to build an implant system to fit the patient's anatomical and physiological requirements. 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.

Device Description – Palisade Pedicular Fixation System

The Palisade Pedicular Fixation System consists of titanium screws and cobalt chrome rods which allow a surgeon to build a spinal implant construct to accommodate the anatomical and physiological needs of the patient. 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.

Intended Use / Indications for Use

The Threshold Pedicular Fixation System and Palisade Pedicular Fixation System 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.

Technological Characteristics

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

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

Non-Clinical Testing

Testing was not required to support this change. Spineology's risk analysis is sufficient to demonstrate the substantial equivalence of the HA-coated Threshold and Palisade pedicle screws to the predicate devices.

Conclusion

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