



Food and Drug Administration  
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Spineology, Incorporated  
Ms. Jacqueline A. Hauge  
Regulatory Affairs Manager  
7800 3<sup>rd</sup> Street North, Suite 600  
Saint Paul, Minnesota 55128

February 23, 2016

Re: K153323

Trade/Device Name: 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: December 3, 2015  
Received: December 4, 2015

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" (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 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)

K153323

Device Name

Palisade Pedicular Fixation System

Indications for Use (Describe)

The Palisade 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:** November 17, 2015

**Submitter:** Spineology Inc.  
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Establishment Registration Number: 2135156

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### Device Name and Classification

**Trade Name:** Palisade Pedicular Fixation System  
**Common Name:** Pedicle Screw System  
**Classification Name:** Orthosis, Spinal Pedicle Fixation  
**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:** K143403 Threshold Pedicular Fixation System

**Additional:** K140010 Fortress Pedicle Screw System  
K122901 Firebird Spinal Fixation System, Phoenix  
MIS Spinal Fixation System

### Device Description

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.

### Indications for Use

The Palisade 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, the Palisade Pedicular Fixation System has the same:

- Intended Use
- Indications for Use
- Fundamental Scientific Technology
- Biological Safety
- Packaging System
- Sterilization Method

### Summary of Performance and Biological Testing

The following performance tests were conducted in accordance with applicable standards and test methods to determine the endurance, strength, and durability of the Palisade Pedicular Fixation System:

#### ASTM F1798

- Axial Grip
- Flexural Grip
- Torsional Grip

#### ASTMF1717

- Static Compression Bending
- Static Torsion
- Dynamic Compression Bending

Packaging and sterilization testing was not required as there was no change to the sterile barrier system, sterilization method, sterilization parameters, or sterility assurance level (SAL) from the predicate device.

Biological safety testing was not required as there was no change in materials from the predicate device.

### Conclusion

Spineology has demonstrated that the Palisade Pedicular Fixation System is substantially equivalent to the predicate devices. The fundamental scientific principle, primary technological characteristics, and intended use are unchanged from the predicate device.