



Food and Drug Administration
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September 2, 2015

Spineology, Incorporated
Ms. Karen Roche
Vice President, Operations & Technology
7800 3rd Street North, Suite 600
Saint Paul, Minnesota 55128

Re: K152148

Trade/Device Name: Fortress™ 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: July 31, 2015
Received: August 3, 2015

Dear Ms. Roche:

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 yours,

Lori A. Wiggins -S

for

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)

K152148

Device Name

Fortress™ Pedicular Fixation System

Indications for Use (Describe)

The Spineology Fortress™ Pedicular Fixation System is intended for posterior, non-cervical fixation as an adjunct to fusion 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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2. 510(k) Summary

Applicant:	Spineology Inc. 7800 3 rd Street N., Suite 600 Saint Paul, MN 55128 Phone: 651-256-8500 Fax: 651-256-8505
Contact Person:	Karen Roche
Date Prepared:	July 31, 2015
Trade Name:	Fortress™ Pedicular Fixation System
Product Classification and Code:	Pedicle Screw Spinal System Class III per 21 CFR 888.3070, Product Codes NKB, MNI, MNH
Predicate Device(s):	Primary: Spineology Fortress Pedicle Screw System [K140010] Additional: Globus Beacon® Stabilization System [K121922]
Device Description:	The Spineology Fortress™ Pedicular Fixation System consists of screws (titanium) and rods (cobalt chrome) to allow the surgeon to build an implant system to fit the patient's anatomical and physiological requirements. The Fortress System screws are available with or without 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 devices are provided sterile. The associated instruments are provided non-sterile.
Intended Use:	The Spineology Fortress™ Pedicular Fixation System is intended for posterior, non-cervical fixation as an adjunct to fusion 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.
Purpose of this 510(k):	The purpose of this submission is to request clearance for adding hydroxyapatite (HA)-coated screws to the Fortress™ System.
Summary of Technological Characteristics:	The subject screws have a hydroxyapatite coating on the screw threads. The base material, thread form, and screw sizes are the same as the predicate devices. The technological characteristics remain the same as the predicate devices with respect to intended use, indications for use, design, fundamental technology, and operational principles.
Testing	Coating characterization/analyses were provided. The results of a risk analysis support a determination that the device is substantially equivalent to the identified predicate devices.
Conclusion:	The information submitted in this premarket notification supports a determination that the Fortress™ Pedicular Fixation System is substantially equivalent in technological characteristics and intended use to the predicate devices.