APR 2 3 2014

510(k) Summary

Applicant:	Spineology Inc. 7800 3rd Street N., Suite 600 Saint Paul, MN 55128 Phone: 651-256-8500 Fax: 651-256-8505
Contact Person:	Karen Roche
Date Prepared:	April 21, 2014
Trade Name:	Spineology Fortress™ Pedicle Screw System
Product Classification and Code:	Class III per 21 CFR 888.3070, Product Codes MNI, MNH, and NKB
Predicate Device(s):	KBB EOS Pedicle Screw System (K082509) and CD Horizon Spinal Fixation System from Medtronic Sofamor Danek (most recent clearance is K132471)
Device Description:	The Spineology Fortress™ Pedicle Screw 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 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 or non-sterile. The associated instruments are provided non-sterile.
Intended Use:	The Spineology Fortress™ Pedicle Screw 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.
Purpose of this 510(k):	New product.
Summary of Technological Characteristics:	The device is shown to be substantially equivalent to the intended use, materials, configuration, and performance characteristics of the predicate products.
Testing	Mechanical testing was performed as follows: flexural grip, torsional grip, and axial grip tests according to F1798-97(2008), axial pullout and torque to failure per ASTM F543-13, static torsion and static and dynamic compression bending according to ASTM F1717-13.
Conclusion:	The information submitted in this premarket notification supports a determination that the devices subject to this submission are substantially equivalent in technological characteristics and intended use to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

April 23, 2014

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

Re: K140010
Trade/Device Name: Fortress™ Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNH, MNI
Dated: March 25, 2014
Received: March 26, 2014

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,

Ronald P. Jean -S for

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)*
K140010

Device Name
Fortress Pedicle Screw system

Indications for Use *(Describe)*
The Spineology Fortress™ Pedicle Screw 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

James P. Bertram -S
2014.04.23 08:47:44 -04'00'

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