

MAY 14 2014

5. 510(K) SUMMARY

Submitter's Name:	SpineFrontier, Inc.
Submitter's Address:	500 Cummings Center, Suite 3500 Beverly, MA 01915, U.S.A.
Submitter's Telephone:	978.232.3990 x116
Contact Person:	Paul L. Speidel Regulatory Affairs Manager Tel: 978.279.9272 Fax: 978.232.3991
Prepared by:	Meredith L. May, MS Empirical Testing Corp. 719.337.7579
Date Summary was Prepared:	April 16 th , 2014
Trade or Proprietary Name:	SpineFrontier® PedFuse® Pedicle Screw System
Common or Usual Name:	Orthosis, Spondylolisthesis Spinal Fixation Orthosis, Spinal Pedicle Fixation
Classification:	Class II per 21 CFR §888.3070
Product Code:	MNH, MNI
Classification Panel:	Orthopedic and Rehabilitation Devices Panel
Predicate Devices:	SpineFrontier® PedFuse® Pedicle Screw System (K123164, K092420) Medtronic TSRH® Spinal System (K091797) Pioneer Quantum Spinal System (K101790) Globus Transition™ Stabilization System (K073439)

DESCRIPTION OF THE DEVICE

The SpineFrontier® PedFuse® Pedicle Screw System is intended to help provide immobilization and stabilization of spinal segments as an adjunct to fusion of the thoracic, lumbar, and/or sacral spine. The system consists of longitudinal rods, polyaxial screws, and cross connector.

CHANGE FROM PREVIOUSLY CLEARED SYSTEM

The purpose of this submission is to make additions to the components of the SpineFrontier® PedFuse® Pedicle Screw System cleared in K123164 and K092420. Hydroxyapatite (HA)-

coated titanium alloy screws and Cobalt Chrome (CoCr) alloy rods are added to the System in this submission.

INDICATIONS FOR USE

The SpineFrontier® PedFuse® Pedicle Screw System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (Pseudarthrosis).

In addition, the SpineFrontier® PedFuse® Pedicle Screw System is indicated for the treatment of severe spondylolisthesis (Grade 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft, with the device fixed or attached to the lumbar and sacral spine.

When used in a percutaneous approach with MIS instrumentation, the SpineFrontier® PedFuse® Pedicle Screw System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, failed previous fusion (Pseudarthrosis) and severe spondylolisthesis (Grade 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft, with the device fixed or attached to the lumbar and sacral spine.

The indications for use for the SpineFrontier® PedFuse® Pedicle Screw System have not changed relative to the previously cleared SpineFrontier® PedFuse® Pedicle Screw System (K123164, K092420). The indications for use of the SpineFrontier® PedFuse® Pedicle Screw System are similar to that of the predicates Medtronic TSRH® Spinal System (K091797), Pioneer Quantum Spinal System (K101790), and Globus Transition™ Stabilization System (K073439).

TECHNICAL CHARACTERISTICS

The subject screw components are fabricated from medical grade titanium alloy (ASTM F136) with hydroxyapatite coating and the subject rod components are fabricated from cobalt chrome alloy (35N LT or ASTM F1537). Titanium alloys, hydroxyapatite coatings, and cobalt chrome alloys have a successful history of use in the spinal implant industry and use of these materials in these devices does not introduce any previously unaccepted patient risks. The Medtronic TSRH® Spinal System (K091797) and the Pioneer Quantum Spinal System (K101790) include screws that are manufactured from titanium alloy with hydroxyapatite coating. The Medtronic TSRH®

Spinal System (K091797) includes components made from medical grade cobalt-chromium-molybdenum alloy, and Pioneer Quantum Spinal System (K101790) includes rods that are manufactured from Cobalt Chrome. The Globus Transition™ Stabilization System includes titanium alloy screws that are hydroxyapatite (HA) coated (ASTM F1185).

PERFORMANCE TESTING SUMMARY

In support of this Special 510(k) Device Modification Premarket Notification, Spine Frontier has conducted mechanical testing to demonstrate that the modifications to the PedFuse® Pedicle Screw System provide adequate and substantially equivalent mechanical strength for their intended use. The PedFuse Pedicle Screw System was tested in the following modes:

- Static Axial Compression Bending (ASTM F1717-13)
- Static Torsion (ASTM F1717-13)
- Cyclic Axial Compression Bending (ASTM F1717-13)
- Custom Instrument Testing

CONCLUSION

The subject modified PedFuse® Pedicle Screw System is very similar to previously cleared PedFuse® Pedicle Screw System. The subject PedFuse® Pedicle Screw System has similar intended uses, indications, technological characteristics and principles of operation as the predicate devices. The modifications raise no new types of safety or effectiveness questions. The overall technology characteristics and mechanical performance data lead to the conclusion that the PedFuse® System is substantially equivalent 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

May 14, 2014

SpineFrontier, Incorporated
Mr. Paul L. Speidel
Regulatory Affairs Manager
500 Cummings Center, Suite 3500
Beverly, Massachusetts 01915

Re: K133153

Trade/Device Name: SpineFrontier® PedFuse® Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNH, MNI
Dated: April 17, 2014
Received: April 18, 2014

Dear Mr. Speidel:

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

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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

4. INDICATIONS FOR USE STATEMENT

Device Name: SpineFrontier® PedFuse® Pedicle Screw System

The SpineFrontier® PedFuse® Pedicle Screw System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (Pseudarthrosis).

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Prescription Use X AND/OR Over-The-Counter Use _____
 (Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER
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Concurrence of Center for Devices and Radiological Health (CDRH)

James P. Bertram -S
 2014.05.14 14:48:31 -04'00'

(Division Sign-Off)
 Division of Orthopedic Devices
 510(k) Number: K133153