DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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February 12, 2015

SpineFrontier, Incorporated
% Mr. Kenneth C. Maxwell II
Empirical Consulting, LLC
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K143377
Trade/Device Name: 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: January 15, 2015
Received: January 16, 2015

Dear Mr. Maxwell:

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,

Mark N. Melkerson -S

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 on last page.

510(k) Number *(if known)*
K143377

Device Name
PedFuse® Pedicle Screw System

Indications for Use *(Describe)*

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 (L3 to S1).

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)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"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."

5. 510(K) SUMMARY

Submitter's Name:	SpineFrontier®
Submitter's Address:	500 Cummings Center, Suite 3500 Beverly, MA 01915
Submitter's Telephone:	978.232.3990 x252
Company Contact Person:	Manthan Damani, MSRA Senior Regulatory Affairs Associate
Official Contact Person:	Kenneth C Maxwell II Empirical Consulting LLC 719.291.6874
Date Summary was Prepared:	2-Feb-15
Trade or Proprietary Name:	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:	87 Orthopedic Panel

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

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 screw assemblies, and cross connectors.

CHANGE FROM PREVIOUSLY CLEARED SYSTEM

The purpose of this submission is to add a component to the SpineFrontier® PedFuse® Pedicle Screw System cleared in K133153, K123164, and K092420. A sliding washer is being 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 (L3 to S1).

The indications for use for the SpineFrontier® PedFuse® Pedicle Screw System have not changed relative to the previously cleared SpineFrontier® PedFuse® Pedicle Screw System (K133153, K123164, K092420).

TECHNICAL CHARACTERISTICS

The subject sliding washer is fabricated from medical grade titanium alloy (ASTM F136). Titanium 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.

Table 5-1 Predicate Devices

510k Number	**Trade or Proprietary or Model Name**	**Manufacturer**	**Predicate Type**
K133153, K123164, K092420	Pedfuse® Pedicle Screw System	SpineFrontier	Primary
K071420	Chameleon® FacetFuse® MIS Screw System	SpineFrontier	Reference

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 previously cleared. The modifications raise no new types of safety or effectiveness questions. The overall technology characteristics lead to the conclusion that the Pedfuse® Pedicle Screw System is substantially equivalent to the predicate devices.