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
Spine Frontier contact Person:	Paul Speidel Regulatory Affairs Manager: 978.232.3991
Prepared by and official contact person:	Meredith L. May, MS Empirical Testing Corp. 719.337.7579
Date Summary was Prepared:	03 January 2014
Trade or Proprietary Name:	SpineFrontier® A-CIFT™ SoloFuse™ Cervical Intervertebral Body Fusion Device
Common or Usual Name:	Intervertebral Fusion Device With Integrated Fixation, Cervical Intervertebral Fusion Device With Bone Graft, Cervical
Classification:	Class II per 21 CFR §888.3080
Product Code:	OVE
Classification Panel:	Orthopedic and Rehabilitation Devices Panel
Predicate Devices:	LDR ROI-C (K091088, K113559) NuVasive CoRoent (K102547)

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The A-CIFT™ SoloFuse™ consists of a PEEK OPTIMA LT1 spacer with titanium bone screws for intervertebral body fusion. Fixation is achieved by inserting bone screws through the openings in the spacer into the vertebral bodies of the cervical spine. The lordotic and non-lordotic PEEK-OPTIMA® LT1 spacers are provided in heights of 5mm to 12mm with a width of 17mm and depths of 13.5mm and 14mm. The lag and rigid screws are offered in diameters 4.2mm and 4.5mm and lengths of 12mm to 16mm. The titanium bone screws traverse the PEEK-OPTIMA® LT1 interbody device either through the body or a posterior/inferior flange to anchor into the patient's vertebral body, thereby securing the interbody into the final placement location. The cage has endplate teeth for additional fixation, ports for bone graft and an anti-screw backout.

INDICATIONS FOR USE

A-CIFT™ SoloFuse™ is intended for stand-alone use for intervertebral body fusion of the spine of skeletally mature patients, using autogenous bone graft to facilitate fusion. The A-CIFT™ SoloFuseTM system must be used with the internal bone screws for fixation. The device is indicated for use in patients with degenerative disc disease (DDD) of the cervical spine at one level from the C2-C3 disc to the C7-T1 disc. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s).

Degenerative Disc Disease is defined as discogenic pain with degeneration of the disc confirmed by a history and radiographic studies. These patients should be skeletally mature and have had six (6) weeks of non-operative treatment prior to the treatment with an intervertebral spacer.

TECHNICAL CHARACTERISTICS

The spacers are manufactured from PEEK-OPTIMA® LT1 (ASTM F2026) and Tantalum (ASTM F560-05) markers. Both materials have a successful history of use in the spinal implant industry and use of it in these devices does not introduce any previously unaccepted patient risks. The LDR ROI-C (K091088, K113559) and NuVasive CoRoent (K102547) are manufactured from PEEK-OPTIMA® LT1 and titanium alloy along with Tantalum markers.

The bone screws are manufactured from titanium alloy meeting requirements of ASTM F136, *Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401).* Titanium alloy has a successful history of use in the spinal implant industry and use of it in these devices does not introduce any previously unaccepted patient risks. The LDR ROI-C (K091088, K113559) and NuVasive CoRoent (K102547) bone screws are also manufactured from titanium alloy.

PERFORMANCE DATA

The A-CIFT™ SoloFuse™ has been tested in the following test modes:

- Static Axial Compression (ASTM F-2077)
- Static Compression-Shear (ASTM F-2077)
- Static Torsion (ASTM F-2077)
- Dynamic Axial Compression (ASTM F-2077)
- Dynamic Compression-Shear (ASTM F-2077)
- Dynamic Torsion (ASTM F-2077)
- Subsidence (ASTM F-2267 and ASTM F-2077)
- Expulsion (ASTM Draft F-04.25.02.02)

The results of this non-clinical testing show that the strength of the A-CIFT™ SoloFuse™ is sufficient for its intended use and legally marketed predicate devices.

CONCLUSION

The overall technology characteristics and mechanical performance data lead to the conclusion that the A-CIFT™ SoloFuse™ is substantially equivalent to the predicate device.

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

January 3, 2014

SpineFrontier, Incorporated
% Empirical Testing Corporation
Meredith May, MS, RAC
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K131880
Trade/Device Name: SpineFrontier® A-CIFT™ SoloFuse™ Cervical Intervertebral Body Fusion Device
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVE
Dated: November 26, 2013
Received: November 29, 2013

Dear Ms. May:

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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® A-CIFT™ SoloFuse™ Cervical Intervertebral Body Fusion Device

A-CIFT™ SoloFuse™ is intended for stand-alone use for intervertebral body fusion of the spine of skeletally mature patients, using autogenous bone graft to facilitate fusion. The A-CIFT™ SoloFuseTM system must be used with the internal bone screws for fixation. The device is indicated for use in patients with degenerative disc disease (DDD) of the cervical spine at one level from the C2-C3 disc to the C7-T1 disc. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s).

Degenerative Disc Disease is defined as discogenic pain with degeneration of the disc confirmed by a history and radiographic studies. These patients should be skeletally mature and have had six (6) weeks of non-operative treatment prior to the treatment with an intervertebral spacer.

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

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Hwang, Ph.D.
Division of Orthopedic Devices