



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

SpineFrontier, Incorporated
% Kenneth C. Maxwell II
Regulatory and Quality Specialist
Empirical Testing Corporation
4628 Northpark Drive
Colorado Springs, Colorado 80918

July 17, 2015

Re: K151198
Trade/Device Name: A-CIFT™ SoloFuse™
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVE
Dated: June 18, 2015
Received: June 19, 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" (21CFR 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

Indications for Use

510(k) Number (if known)

K151198

Device Name

A-CIFT™ SoloFuse™

Indications for Use (Describe)

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™ SoloFuse™ 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.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

“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.”

510(k) Summary

Submitter's Name:	Spine Frontier, Inc.
Submitter's Address:	500 Cummings Center, Suite 3500 Beverly, MA 01915
Submitter's Telephone:	978.232.3990 x252
Company Contact Person:	Manthan Damani, MSRA Associate Manager, Regulatory Affairs
Contact Person:	Kenneth C Maxwell II Empirical Consulting LLC 719.291.6874
Date Summary was Prepared:	18 June 2015
Trade or Proprietary Name:	A-CIFT™ SoloFuse™
Common or Usual Name:	Intervertebral Body Fusion Device
Classification:	Class II per 21 CFR §888.3080
Product Code:	OVE
Classification Panel:	Orthopedic Devices

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION

The A-CIFT™ SoloFuse™ consists of a PEEK 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. System is provided non-sterile with instructions for sterilization. The lordotic and non-lordotic PEEK 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.

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™ SoloFuse™ 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. The bone screws are manufactured from titanium alloy meeting requirements of ASTM F136.

Table 5-1 Predicate Devices

510k Number	Trade or Proprietary or Model Name	Manufacturer	Type
K131880	A-CIFT™ SoloFuse™	SpineFrontier®	Primary
K102547	CoRent® Small Interlock™ System	NuVasive®	Reference

PERFORMANCE TESTING SUMMARY

No performance testing is being included as part of this submission.

REASON FOR SUBMISSION

The purpose of this submission is to include additional surgical instruments with an optional freehand surgical technique for the SpineFrontier A-CIFT™ SoloFuse™.

CONCLUSION

The subject modified A-CIFT™ SoloFuse™ is very similar to previously cleared A-CIFT™ SoloFuse™. The subject A-CIFT™ SoloFuse™ 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 lead to the conclusion that the A-CIFT™ SoloFuse™ is substantially equivalent to the predicate device.