May 8, 2018

SpineFrontier, Inc.
% Meredith L May
Empirical Testing Corp.
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K172484
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, ODP
Dated: April 13, 2018
Received: April 17, 2018

Dear Meredith 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172484

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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510(K) SUMMARY

Submitter's Name:	SpineFrontier, Inc.
Submitter's Address:	350 Main Street, 3rd Floor Malden, MA 02148
Submitter's Telephone:	978.232.3990 x275
Company Contact Person:	Director of Innovation
Contact Person:	Meredith L May MS, RAC Empirical Consulting LLC 719-337-7579
Date Summary was Prepared:	13 December 2017
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, ODP
Classification Panel:	Division of Orthopedic Devices

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The A-CIFT™ SoloFuse™ consists of a PEEK or PEEK-OPTIMA HA Enhanced 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 A-CIFT™ SoloFuse™ PEEK-OPTIMA HA Enhanced implants are provided sterile and irradiated by gamma radiation. The A-CIFT™ SoloFuse™ PEEK implants are provided non-sterile with instructions for sterilization. The lordotic and non-lordotic PEEK or PEEK-OPTIMA HA Enhanced spacers are provided in various sizes. The lag and rigid screws are offered in various diameters and lengths.

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.

TECHNOLOGICAL CHARACTERISTICS

The spacers are manufactured from PEEK-OPTIMA HA Enhanced and 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	Predicate Type
K151198	A-CIFT™ SoloFuse™	SpineFrontier	Primary
K142026	Arena-C® HA PEEK Cervical IBFD	SpineFrontier	Additional

PERFORMANCE TESTING SUMMARY

No performance testing is being included as part of this submission. Failure Effects Analysis (FEA) was used *in lieu* of mechanical testing to show substantial equivalence to the previously cleared design.

REASON FOR SUBMISSION

The purpose of this submission is to manufacture the SpineFrontier, Inc. A-CIFT™ SoloFuse™ from PEEK-OPTIMA HA Enhanced.

CONCLUSION

The overall technology characteristics and mechanical performance data lead to the conclusion that the SpineFrontier, Inc. A-CIFT™ SoloFuse™ is safe and effective and substantially equivalent to the previously cleared product.