June 19, 2020

SpineFrontier, Inc.
Omkar Joglekar
Quality Manager
350 Main St, 2nd Floor
Malden, Massachusetts 02148

Re: K193106
Trade/Device Name: SpineFrontier Lumbar Interbody Fusion Device System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: May 22, 2020
Received: May 26, 2020

Dear Omkar Joglekar:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Brent L. Showalter, Ph.D.
Acting Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020

Indications for Use

510(k) Number *(if known)*
K193106

Device Name
SpineFrontier Lumbar Interbody Fusion Device System

Indications for Use *(Describe)*

The SpineFrontier Lumbar lnterbody Fusion Device System (Dorado IBC, Dorado PLIFT, Dorado ELIFT, Arena-L, Dorado TILT, Dorado TLIFT, Dorado Wide, and Ursa S-LIFT) is intended for intervertebral body fusion of the spine of skeletally mature patients, using autogenous bone graft to facilitate fusion. The device is indicated for use in patients with degenerative disc disease (DDD) at one or two contiguous spinal levels from L2-S1. 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 back pain with degeneration of the disc confirmed by history or radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment.

The SpineFrontier Lumbar Interbody Fusion Device System is intended to be used with supplemental spinal fixation system(s) cleared for use in the lumbar spine.

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.

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510(K) SUMMARY

Submitter's Name:	SpineFrontier, Inc.
Submitter's Address:	350 Main Street Malden, MA 02148
Submitter's Telephone:	978.232.3990 Ext-107
Contact Person:	Omkar Joglekar, SpineFrontier, Inc. omkarjoglekar@kicventures.com
Date Summary was Prepared:	05/22/2020
Trade or Proprietary Name:	SpineFrontier Lumbar Interbody Fusion Device System
Common or Usual Name:	Intervertebral Fusion Device With Bone Graft, Lumbar
Classification:	Class II per 21 CFR §888.3080
Product Code:	MAX
Classification Panel:	Division of Orthopedic Devices

The purpose of this submission is to expand implant profiles offered for greater lordosis and curvature profile and to replace the titanium coating for the previously cleared implant with a new titanium coating for the SpineFrontier Lumbar Interbody Fusion Device System Dorado P-LIFT, Dorado T-LIFT, and Ursa S-LIFT for implants with a length of 24 mm or longer.

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The SpineFrontier Lumbar Interbody Fusion Device System is a spinal intervertebral body fusion device system intended for intervertebral body fusion of the spine of skeletally mature patients, using autogenous bone graft to facilitate fusion. The system is comprised of devices made of PEEK Optima® LT1 or titanium coated PEEK Optima® LT1, with varying widths, lengths, and heights to fit the anatomical needs of patients. The devices have raised contours on the superior and inferior surfaces that will resist device movement following implantation.

INDICATIONS FOR USE

The SpineFrontier Lumbar lnterbody Fusion Device System (Dorado IBC, Dorado PLIFT, Dorado ELIFT, Arena-L, Dorado TILT, Dorado TLIFT, Dorado Wide, and Ursa S-LIFT) is intended for intervertebral body fusion of the spine of skeletally mature patients, using autogenous bone graft to facilitate fusion. The device is indicated for use in patients with degenerative disc disease (DDD) at one or two contiguous spinal levels from L2-S1. 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 back pain with degeneration of the disc confirmed by history or radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment.

The SpineFrontier Lumbar Interbody Fusion Device System is intended to be used with supplemental spinal fixation system(s) cleared for use in the lumbar spine.

TECHNICAL CHARACTERISTICS

The SpineFrontier Lumbar Interbody Fusion Device System is made from PEEK Optima® LT1 per ASTM F2026 with Tantalum markers per ASTM F560 and Titanium Coating per ASTM F1580. The subject and predicate devices have nearly identical technological characteristics and the minor differences do not raise any new issues of safety and effectiveness. Specifically the following characteristics are identical between the subject and predicates:

- Indications for Use
- Materials of manufacture
- Structural support mechanism
    - Specifically, the implant geometry between the vertebral body interfacing teeth geometry
- Principles of operation

Table 5-1 Predicate Devices

510k Number	Trade or Proprietary or Model Name	Manufacturer	Designation
K142504	SpineFrontier Lumbar Interbody Fusion Device System	SpineFrontier, Inc.	Primary

PERFORMANCE TESTING SUMMARY

In support of this Special 510(k) Device Modification Premarket Notification, engineering rationale was performed in lieu of bench testing. No performance data was required because none of the modifications to the subject from its previous clearance under K142504 present a worst case for mechanical testing to the worst case tested for that clearance.

CONCLUSION

The modified SpineFrontier Lumbar Interbody Fusion Device System subject is very similar to previously cleared SpineFrontier Lumbar Interbody Fusion Device System (K142504). The subject SpineFrontier Lumbar Interbody Fusion Device System has the same intended uses, indications, technological characteristics, and principles of operation as the predicate SpineFrontier Lumbar Interbody Fusion Device System. The modifications raise no new types of safety or effectiveness questions. The overall technology characteristics and the rationale for not including mechanical performance data lead to the conclusion that the subject SpineFrontier Lumbar Interbody Fusion Device System is substantially equivalent to the predicate.