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

March 29, 2017

FacetLINK dba LINKSpine
% Kenneth C. Maxwell II
Regulatory and Quality Specialist
Empirical Testing Corp.
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K162693
Trade/Device Name: VertebraLINK Fusion Platform
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: March 3, 2017
Received: March 8, 2017

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,

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)*
K162693

Device Name
VertebraLINK Fusion Platform

Indications for Use *(Describe)*

The VertebraLINK Fusion Platform is indicated for use in patients with degenerative disc disease (DDD) at one or two levels from L2 to S1. These DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These implants may be implanted via an open or a minimally invasive posterior approach. Alternatively, these implants may also be implanted via posterior and/or transforaminal approach. These implants are to be used with autogenous bone graft. These devices are intended to be used with supplemental fixation instrumentation, which has been cleared by the FDA 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)

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)*

510(K) SUMMARY

Submitter's Name:	FacetLINK dba LINKSpine
Submitter's Address:	101 Roundhill Drive Rockaway, NJ 07866
Submitter's Telephone:	973.627.4171
Contact Person:	Kenneth C. Maxwell II Empirical Testing Corp. 719.291.6874
Date Summary was Prepared:	23 March2016
Trade or Proprietary Name:	VertebraLINK Fusion Platform
Common or Usual Name:	Intervertebral Fusion Device With Bone Graft, Lumbar
Classification:	Class II per 21 CFR §888.3080 Device Classification
Product Code:	MAX
Classification Panel:	Division of Orthopedic Devices

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION

The VertebraLINK Fusion Platform is a comprehensive suite of generally box shaped devices which can be implanted into the prepared disc space when performing an intervertebral body fusion. The devices are manufactured from Invibio's PEEK Optima LT1 or PEEK Optima HA Enhanced per ASTM F2026. The devices contain a central axial opening for packing of bone graft material as well as teeth on the inferior and superior surfaces to resist expulsion. The platform will be offered in multiple lengths, widths, heights and lordoses to accommodate varying anatomies, pathologies, surgeon preferences, or techniques (i.e., TLIF, PLIF, or Oblique PLIF). Additionally, the device contains radiographic markers made from tantalum per ASTM F560.

INDICATIONS FOR USE

The VertebraLINK Fusion Platform is indicated for use in patients with degenerative disc disease (DDD) at one or two levels from L2 to S1. These DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These implants may be implanted via an open or a minimally invasive posterior approach. Alternatively, these implants may also be implanted via posterior and/or transforaminal approach. These implants are to be used with autogenous bone graft. These devices are intended to be used with supplemental fixation instrumentation, which has been cleared by the FDA for use in the lumbar spine.

Table 5-1: Predicate Devices

510k Number	Trade or Proprietary or Model Name	Manufacturer	Predicate Type
K130573	Interbody System	Tyber Medical	Primary
K112095	AccuLiF® TL-PEEK Cage and AccuLiF® TL and PL	CoAlign Innovation	Additional
K113478	PLIF Cage	Eisertech	Additional
K151785	Px HA™ PEEK IBF System	Innovasis	Reference

PERFORMANCE DATA

The following testing has been completed as part of the VertebraLINK Fusion Platform submission:

- Static axial compression per ASTM F2077
- Dynamic axial compression per ASTM F2077
- Expulsion per ASTM Draft Standard F-04.25.02.02
- Subsidence per ASTM F2267
- Bacterial Amebocyte Lysate (LAL) testing per AAMI ST72

The results of this non-clinical testing show that the strength of the VertebraLINK Fusion Platform is sufficient for its intended use and is substantially equivalent to legally marketed predicate devices.

TECHNOLOGICAL CHARACTERISTICS

The following technological characteristics are similar between the VertebraLINK Fusion Platform and the predicate devices:

- Principles of Operation
- Indications for Use
- Materials
- Sterility
- Dimensional Features

CONCLUSION

The overall technology characteristics and mechanical performance data lead to the conclusion that the VertebraLINK Fusion Platform is substantially equivalent to the predicate device.