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

July 7, 2016

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

Re: K160722
Trade/Device Name: CorticaLINK Spinal Fusion Platform
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNI, MNH
Dated: June 6, 2016
Received: June 9, 2016

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 yours,

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)*
K160722

Device Name
CorticaLINK Spinal Fusion Platform

Indications for Use *(Describe)*

The CorticaLINK Spinal Fusion Platform is intended for non-cervical pedicle fixation as an adjunct to fusion for the following acute and chronic instabilities or deformities for the T1-S1 vertebrae in skeletally mature patients:

- degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies);
- spondylolisthesis;
- trauma (i.e., fracture or dislocation);
- spinal stenosis;
- curvatures (i.e., scoliosis, kyphosis, and/or lordosis);
- tumor;
- pseudoarthrosis;
- and failed previous fusion.

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)*

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5. 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 Consulting 719.291.6874
Date Summary was Prepared:	06 June 2016
Trade or Proprietary Name:	CorticaLINK Spinal Fusion Platform
Common or Usual Name:	Orthosis, Spinal Pedicle Fixation Orthosis, Spondylolisthesis Spinal Fixation Orthosis, Spinal Pedicle Fixation, For Degenerative Disc Disease
Classification:	Class III
Product Code:	NKB, MNI, MNH
Classification Panel:	Division of Orthopedic Devices

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The CorticaLINK Spinal Fusion Platform is a comprehensive suite of fixation implants which can be used to stabilize the spine as an adjunct to fusion following surgical decompression. The platform is comprised of screws, rods and locking caps, with the screws being offered in several different lengths, diameters, and thread pitches to accommodate varying anatomies, pathologies, and surgeon preferences.

INDICATIONS FOR USE

The CorticaLINK Spinal Fusion Platform is intended for non-cervical pedicle fixation as an adjunct to fusion for the following acute and chronic instabilities or deformities for the T1-S1 vertebrae in skeletally mature patients:

- degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies);
- spondylolisthesis;
- trauma (i.e., fracture or dislocation);
- spinal stenosis;
- curvatures (i.e., scoliosis, kyphosis, and/or lordosis);
- tumor;
- pseudoarthrosis;

- and failed previous fusion.

The indications for use for the CorticaLINK Spinal Fusion Platform is similar to that of the predicate devices in Table 5-1.

TECHNOLOGICAL CHARACTERISTICS

The intended use and technological features of the CorticaLINK Spinal Fusion Platform do not substantially differ from the legally marketed predicate devices. The predicate devices and the CorticaLINK Spinal Fusion Platform are designed for posterior stabilization to provide immobilization and stabilization of spinal segments as an adjunct to fusion.

Table 5-1 Predicate Devices

510k Number	**Trade or Proprietary or Model Name**	**Manufacturer**	**Predicate Type**
K000236	Synergy VLS Open	Interpore	Primary
K050979	S4 Spinal System	Aesculap®, Inc.	Additional
K111940	S 100 Pedicle Screw System	Renovis	Additional

PERFORMANCE DATA

The CorticaLINK Spinal Fusion Platform has been tested in the following test modes:

- Static axial compression bending per ASTM F1717-14
- Dynamic axial compression bending fatigue per ASTM F1717-14
- Static torsion per ASTM F1717-14
- Static screw-shaft pull-through testing
- Static screw-shaft lever out testing

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

CONCLUSION

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