



December 11, 2017

LinkSPINE, Inc.  
Mr. Nickolas G. Kriska  
Director of Engineering  
5950 Symphony Woods Road, Suite 620  
Columbia, Maryland 21044

Re: K173484

Trade/Device Name: CorticalINK Spinal Fusion Platform  
Regulation Number: 21 CFR 888.3070  
Regulation Name: Thoracolumbosacral pedicle screw system  
Regulatory Class: Class II  
Product Code: NKB  
Dated: November 14, 2017  
Received: November 15, 2017

Dear Mr. Kriska:

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

  
Ronald P. Jean -S for

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)

K173484

Device Name

CorticalINK Spinal Fusion Platform

Indications for Use (Describe)

The CorticalINK Fusion System is intended for noncervical 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)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

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  
[PRAStaff@fda.hhs.gov](mailto:PRAStaff@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

### ADMINISTRATIVE INFORMATION

Manufacturer Name: LinkSPINE, Inc.  
(formerly known as FacetLINK Inc. dba Linkspine)  
5950 Symphony Woods Rd.  
Suite 620  
Columbia, MD 21044  
Telephone (410) 772-5465

Official Contact: Nickolas G. Kriska  
Director of Engineering

Date Prepared: November 8, 2017

### DEVICE NAME

Trade/Proprietary Name: CorticalINK Spinal Fusion Platform

Classification Panel: Division of Orthopedic Devices

Common Name: Thoracolumbosacral Pedicle Screw System

Classification: Class II per 21 CFR §888.3070

Product Code(s): NKB

### ESTABLISHMENT REGISTRATION NUMBER

The LinkSPINE, Inc. (formerly known as FacetLINK Inc. dba Linkspine) establishment registration number is 3009442592.

### INTENDED 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.

### DEVICE DESCRIPTION

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.

The systems components are manufactured using standard manufacturing processes of medical grade Titanium alloy (Ti6Al4V) that complies with ASTM F136 – *Standard Specifications for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications*, Commercially Pure Grade4 Titanium (CP Ti) per ASTM F67 – *Standard Specifications for Unalloyed Titanium for Surgical Implant Applications (UNS R50250, R50400, R50500 & R50700)* and Cobalt Chromium (CrCo) per ASTM F75 - *Standard Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Castings and Casting Alloy for Surgical Implants (UNS R30075)*.

The implant components are provided clean and non-sterile. These devices are supplied in a rigid sterilization tray and are to be sterilized by a healthcare professional using a Steam Autoclave in accordance with the instructions for use provided by LinkSPINE, Inc., as well as the instructions provided by the Autoclave manufacturer.

### **EQUIVALENCE TO MARKETED PRODUCT**

LinkSPINE, Inc. has submitted information to demonstrate that, for the purposes of FDA's regulation of medical devices, the CorticalINK Spinal Fusion Platform is substantially equivalent to the predicate device based on a comparison including the following characteristics:

- FDA Product Code
- Intended Uses
- Anatomical Region
- Implant Materials
- Product Features

### **PRIMARY PREDICATE DEVICE**

- LinkSPINE, Inc. – CorticalINK Spinal Fusion Platform (K160722)

### **PERFORMANCE COMPARISON**

LinkSPINE, Inc. has submitted information to demonstrate that, for the purposes of FDA's regulation of medical devices, the CorticalINK Spinal Fusion Platform modifications substantially meets the performance criteria established for the cleared parent device.

The modified device is used to treat the same indications for use, utilizes the same scientific and operational principles, and is manufactured using the same manufacturing practices from identical materials as the parent device.