Spine Smith Holdings, LLC
Nickolas G. Kriska
Director of Engineering
4719 South Congress Ave.
Austin, Texas 78745

Re: K193465
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: December 10, 2019
Received: December 16, 2019

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. 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,

for RPJ

(Ronald Jean) Vacant
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

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193465

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)

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

ADMINISTRATIVE INFORMATION

Manufacturer Name:	Spine Smith Holdings, LLC 4719 South Congress Ave. Austin, TX 78745 Telephone (512) 637-6745
Official Contact:	Nickolas G. Kriska Director of Engineering
Date Prepared:	December 10, 2019

DEVICE NAME

Trade/Proprietary Name:	CorticaLINK Spinal Fixation Platform
Classification Panel:	Orthopedics
Common Name:	Thoracolumbosacral Pedicle Screw System
Classification:	Class II per 21 CFR §888.3070
Product Code(s):	NKB

ESTABLISHMENT REGISTRATION NUMBER

The Spine Smith Holdings, LLC is listed under the establishment registration number 3006404071.

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. The tulips, screw shafts, and one family of rods are of medical grade Titanium alloy (Ti6AI4V) that complies with ASTM F136 – *Standard Specifications for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications*. The push plate is of Commercially Pure Grade4 Titanium (CP Ti) per ASTM F67 – *Standard Specifications for Unalloyed Titanium for Surgical Implant Applications (UNS R50250, R50400, R50500 & R50700).* The other family of rods are of Cobalt Chromium (CoCr) 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 Spine Smith Holdings, LLC, as well as the instructions provided by the Autoclave manufacturer.

EQUIVALENCE TO MARKETED PRODUCT

Spine Smith Holdings, LLC 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(s)
- Intended Uses
- Anatomical Region
- Implant Materials
- Product Features

PREDICATE DEVICE(S)

- LinkSPINE, Inc. – CorticaLINK Spinal Fusion Platform (K160722) (Primary Predicate)

PERFORMANCE TESTING

The worst-case subject device was tested according to ASTM F1717 in static and dynamic compression bending as well as static torsion. Results of the testing demonstrate substantially equivalent mechanical performance as compared to the predicate(s).

CONCLUSION

Spine Smith Holdings, LLC 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.