August 9, 2022

CoreLink, LLC
% Nathan Wright
Engineer and Regulatory Specialist
Empirical Technologies
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K221776
Trade/Device Name: NextGen Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB
Dated: June 17, 2022
Received: June 21, 2022

Dear Nathan Wright:

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

Colin O'Neill, M.B.E.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221776

Device Name
NextGen Pedicle Screw System

Indications for Use *(Describe)*

The CoreLink NextGen Pedicle Screw System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of thoracic, lumbar, and sacral/iliac spine (T1 – S1/Ilium): degenerative disc disease (defined as discogenic back pain with degeneration of disc confirmed by history and radiographic studies), degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).
When used for posterior non-cervical screw fixation in pediatric patients, the CoreLink NextGen Pedicle Screw System is indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. Additionally, the CoreLink NextGen Pedicle Screw System is intended to treat pediatric patients diagnosed with the following conditions: spondylolisthesis/spondylolysis, and fracture caused by tumor and/or trauma. Pediatric pedicle screw fixation is limited to a posterior approach and is intended to be used with autograft and/or allograft.

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:	CoreLink, LLC
Submitter's Address:	2072 Fenton Logistics Park St. Louis, Missouri 63026
Submitter's Telephone:	888-349-7808
Contact Person:	Nathan Wright MS Empirical Technologies 1-719-351-0248 nwright@empiricaltech.com
Date Summary was Prepared:	June 17, 2022
Trade or Proprietary Name:	NextGen Pedicle Screw System
Common or Usual Name:	Thoracolumbosacral Pedicle Screw System
Classification:	Class II per 21 CFR §888.3070
Product Code:	NKB
Classification Panel:	Orthopedic – Spinal Devices (DHT6B)

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The NextGen Pedicle Screw System is a thoracolumbosacral pedicle screw system containing metallic implants intended to provide immobilization and stabilization of spinal segments. The system consists of traditional pedicle screw assemblies or modular tulip heads with modular screw shanks with extended tab reduction tulip or closed head tulip options, cross-link connectors, set screws, and spinal rods. Components are offered in various shapes and sizes to meet the requirements of the individual patient anatomy.

Implants in the NextGen Pedicle Screw System are manufactured from titanium alloy Ti-6Al-4V per ASTM F136 and cobalt chromium alloy Co-28Cr-6Mo per ASTM F1537.

INDICATIONS FOR USE

The CoreLink NextGen Pedicle Screw System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of thoracic, lumbar, and sacral/iliac spine (T1 – S1/Ilium): degenerative disc disease (defined as discogenic back pain with degeneration of disc confirmed by history and radiographic studies), degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

When used for posterior non-cervical screw fixation in pediatric patients, the CoreLink NextGen Pedicle Screw System is indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. Additionally, the CoreLink NextGen Pedicle Screw System is intended to treat pediatric patients diagnosed with the following conditions: spondylolisthesis/spondylolysis, and fracture caused by tumor and/or trauma. Pediatric pedicle screw fixation is limited to a posterior approach and is intended to be used with autograft and/or allograft.

TECHNOLOGICAL CHARACTERISTICS

The subject and predicate devices have nearly identical technological characteristics and the minor differences do not raise any new issues of safety and effectiveness. The subject device is the same or similar to the predicate devices in the following ways:

- Indications for Use
- Materials
- Component Selection
- Component Sizes
- Biocompatibility

The differences in modular tulip head components do not affect the safety and efficacy of the subject device since mechanical testing was conducted to show substantial equivalence in device bench testing performance.

Predicate Devices

510k Number	Trade or Proprietary or Model Name	Manufacturer	Product Code	Predicate Type
K210539	CoreLink Midline Fixation System	CoreLink, LLC	NKB	Primary
K211323	ASTRA Spine System	SpineCraft, LLC	NKB, KWP, KWQ	Additional
K180179	Firebird Spinal Fixation System	Orthofix Inc.	NKB	Additional

PERFORMANCE DATA

The NextGen Pedicle Screw System has been tested in the following test modes:

- Static compression bending per ASTM F1717
- Static torsion per ASTM F1717
- Dynamic compression bending per ASTM F1717
- Axial grip per ASTM F1798
- Torsion grip per ASTM F1798
- Tulip shank disassociation per ASTM F1798

The results of this non-clinical testing show that the strength of the NextGen Pedicle Screw System 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 NextGen Pedicle Screw System is substantially equivalent to the predicate device.