CoreLink, LLC
% Nathan Wright
Engineer & Regulatory Specialist
Empirical Testing Corp.
4628 Northpark Drive
Colorado Springs, Colorado 80918

April 15, 2021

Re: K210539
Trade/Device Name: CoreLink Midline Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB
Dated: February 15, 2021
Received: February 24, 2021

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: 06/30/2020
See PRA Statement on last page.

510(k) Number *(if known)*
K210539

Device Name
CoreLink Midline Fixation System

Indications for Use *(Describe)*

The CoreLink Midline Fixation 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 Midline Fixation System is indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. Additionally, the CoreLink Midline Fixation 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.

5. 510(K) SUMMARY

Submitter's Name:	CoreLink, LLC
Submitter's Address:	2072 Fenton Logistics Park Blvd. St. Louis, Missouri 63026
Submitter's Telephone:	888-349-7808
Contact Person:	Nathan Wright MS Empirical Testing Corp. 719-351-0248 nwright@empiricaltech.com
Date Summary was Prepared:	February 15, 2021
Trade or Proprietary Name:	CoreLink Midline Fixation System
Common or Usual Name:	Thoracolumbosacral Pedicle Screw System
Classification:	Class II per 21 CFR §888.3070
Product Code:	NKB
Classification Panel:	Orthopedic

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The CoreLink Midline Fixation System is a thoracolumbosacral pedicle screw system containing metallic implants intended to provide immobilization and stabilization of spinal segments. The system consists of polyaxial screws, extended tab reduction tulips, 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.

All screw shanks, set screws, and cross-connectors are manufactured from medical grade titanium alloy (Ti-6Al-4V ELI) per ASTM F136. The screw tulip heads which are modularly attached to the screw shafts by the surgeon during operation are manufactured from medical grade cobalt chrome (Co-28Cr-6Mo) per ASTM F1537, Ti-6Al-4V ELI per ASTM F136, and Nitinol per ASTM F2063. Once the polyaxial screws are affixed into the bone, immobilization and stabilization is achieved by connecting each spinal segment to a spinal rod. Rod components are manufactured from medical grade titanium alloy (Ti-6AL-4V ELI) per ASTM F136 or cobalt chrome (Co-28Cr-6Mo) per ASTM F1537.

INDICATIONS FOR USE

The CoreLink Midline Fixation 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).

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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 similar to predicate device in the following ways:

- Indications for Use
- Materials
- Components
- Sizes
- Surgical Approach
- Biocompatibility
- Mechanical Performance

The difference between the subject and predicates is which components contain nitinol; this difference does not present a concern for safety and effectiveness because nitinol is a common material in spinal implants.

Table 5-1 Predicate Devices

510k Number	**Trade or Proprietary or Model Name**	**Manufacturer**	**Predicate Type**
K131250, K120696, K110321	Tiger Spine System	CoreLink, LLC	Primary
K190360	LineSider™ Spinal Screw	Integrity Implants, Inc	Additional
K180179 K171082	JANUS Midline Fixation System	Orthofix Inc.	Additional
K173130	Reform® Midline Cortical Screw System	Precision Spine, Inc.	Additional
K100952	Synthes Matrix System	Synthes Spine	Additional
K181390	Response Spine System	OrthoPediatrics, Corp.	Additional
K163104	Terrace™ Anterior Cervical Plate System	CoreLink, LLC	Reference

PERFORMANCE DATA

The CoreLink Midline Fixation 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
- A-P per ASTM F1798

The results of this non-clinical testing show that the strength of the CoreLink Midline Fixation 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 CoreLink Midline Fixation System is substantially equivalent to the predicate device.