June 12, 2019

CoreLink, LLC
% Meredith L. May, MS, RAC
Vice President
Empirical Consulting LLC
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K190016
Trade/Device Name: Lateral Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: May 7, 2019
Received: May 8, 2019

Dear Ms. May:

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 CAPT Raquel Peat, PhD, MPH, USPHS
Director
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)*
K190016

Device Name
Lateral Plate System

Indications for Use *(Describe)*

The CoreLink Lateral Plate System (LPS) is intended for use as a laterally placed supplemental fixation device via the lateral or anterolateral surgical approach above the bifurcation of the great vessel or via the anterior surgical approach, below the bifurcation of the great vessels. The CoreLink LPS is designed to provide temporary stability until fusion is achieved. It is intended for lateral or anterolateral lumbar (L1-S1) fixation for the following indications: degenerative disc disease (DDD) (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), deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis, and failed previous fusion.

Alternatively, the CoreLink LPS may remain attached to CoreLink Lateral lumbar interbody devices after implantation. In this configuration the CoreLink LPS must only be used to treat patients with degenerative disk disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels.

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
Submitter's Address:	2072 Fenton Logistics Park Blvd. St. Louis, Missouri 63026
Submitter's Telephone:	888-349-7808
Contact Person:	Meredith Lee May MS, RAC Empirical Consulting 719.337.7579 Mmay@EmpiricalConsulting.com
Date Summary was Prepared:	8 Jan 19
Trade or Proprietary Name:	Lateral Plate System
Common or Usual Name:	Appliance, Fixation, Spinal Intervertebral Body
Classification:	Class II per 21 CFR §888.3060 Spinal Intervertebral Body Fixation Orthosis
Product Code:	KWQ
Classification Panel:	Orthopedic Review Panel

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The CoreLink Lateral Plate System (LPS) is comprised of a lumbar plate and screws. The lumbar plate has a sliding, spring loaded lock tab for each screw position to prevent back-out of the screw. The plate is available in a 2-screw or 4-screw version and in multiple lengths for single level fixation. The screws are available in various lengths and 2 diameters.

INDICATIONS FOR USE

The CoreLink Lateral Plate System (LPS) is intended for use as a laterally placed supplemental fixation device via the lateral or anterolateral surgical approach above the bifurcation of the great vessel or via the anterior surgical approach, below the bifurcation of the great vessels. The CoreLink LPS is designed to provide temporary stability until fusion is achieved. It is intended for lateral or anterolateral lumbar (L1-S1) fixation for the following indications: degenerative disc disease (DDD) (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), deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis, and failed previous fusion.

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TECHNOLOGICAL CHARACTERISTICS

Lateral Plate System plates are made from Ti-6Al-4V ELI in accordance with ASTM F136, and the lock springs are manufactured from Nitinol per ASTM F2063. The subject and predicate devices have nearly identical technological characteristics and the minor differences do not raise any new issues of safety and effectiveness. Specifically the following characteristics are identical between the subject and predicates:

- Indications for Use
- Intended Use
- Implant sizes
- Manufacturing

Table 5-1 Predicate Devices

510k Number	**Trade or Proprietary or Model Name**	**Manufacturer**	**Predicate Type**
K120092	Plymouth Plate System	Globus	Primary
K131533	CAYMAN	K2M	Additional
K150449	LITe	Stryker	Additional
K091044	Accufit ALP System	Spinal USA (Precision Spine)	Additional
K082187	Valiant Anterior Lumbar Plate System	Biomet Spine	Additional
K111866	Halo II Anterior Lumbar Plate System	NuVasive	Additional
K163104	Terrace™ Anterior Cervical Plate System	CoreLink, LLC	Additional

PERFORMANCE DATA

The Lateral Plate System has been tested in the following test modes:

- Static axial compression bending per ASTM F1717
- Static torsion per ASTM F1717
- Dynamic axial compression bending fatigue per ASTM F1717
- Static pull apart testing

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