December 8, 2023

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

Re: K231743
Trade/Device Name: F3D Lateral Lumbar Interbody System, CL5 Lateral Lumbar Interbody System, and Oro Lateral Plate System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX, OVD, KWQ
Dated: November 14, 2023
Received: November 15, 2023

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Brent Showalter -S

Brent Showalter, Ph.D.
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.

Submission Number *(if known)*

K231743

Device Name

F3D Lateral Lumbar Interbody System, CL5 Lateral Lumbar Interbody System, and Oro Lateral Plate System

Indications for Use *(Describe)*

The F3D Lateral Lumbar Interbody System is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). F3D Lateral Lumbar implants are to be used with autogenous bone graft and supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

Hyperlordotic interbody devices (≥20° lordosis) must be used in conjunction with the Oro Lateral plate for fixation. If using the 1-hole CoreLink Oro Lateral Plate System, additional supplemental fixation is required (e.g. posterior fixation).

The CL5 Lumbar Cage is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). CL5 Lumbar implants are to be used with autogenous bone graft and supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

The CoreLink Oro Lateral Plate System (LPS), in two and four-hole configurations, 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 Oro Lateral Plate System 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, pseudarthrosis, and failed previous fusion.

Alternatively, the CoreLink Oro Lateral Plate System may remain attached to CoreLink Lateral lumbar interbody devices after implantation. In this configuration the CoreLink Oro 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.

The CoreLink Oro LPS, one-hole configuration is intended for use in conjunction with traditional supplemental fixation to maintain the relative position of interbody spacers during spinal fusion. The one-hole plate is not intended for use in load-bearing applications.

Hyperlordotic interbody devices (≥20° lordosis) must be used in conjunction with the CoreLink Oro

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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K231743 - 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, RAC Empirical Technologies 1-719-351-0248 nwright@empiricaltech.com
Date Summary was Prepared:	November 14, 2023
Trade or Proprietary Name:	F3D Lateral Lumbar Interbody System, CL5 Lateral Lumbar Interbody System, and Oro Lateral Plate System
Device Classification Name:	Intervertebral Fusion Device with Bone Graft – Lumbar Intervertebral Fusion Device with Integrated Fixation – Lumbar Appliance, Fixation, Spinal Intervertebral Body
Classification & Regulation #:	888.3080 888.3060
Product Code:	MAX, OVD, KWQ
Classification Panel:	Orthopedic – Spinal (DHT6B)

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The F3D Lateral Lumbar Interbody System, additively manufactured Ti-6Al-4V ELI per ASTM F3001 implants, and the CL5 Lateral Lumbar Interbody System, PEEK implants per ASTM F2026 with Tantalum per ASTM F560, are lumbar interbody spacers designed to provide mechanical support to the lumbar spine while arthrodesis occurs. The lateral lumbar spacers with hollow footprints for placement of graft material feature a wide variety of footprint, height, and lordosis options to accommodate patient anatomical needs. The F3D spacers are designed with a porous surface to optimize bone in-growth. The CL5 spacers are designed with ridges on the superior and inferior surfaces to improve grip against the end-plates and prevent expulsion.
The Oro Lateral Plate System consists of plates and screws intended for use as a laterally placed supplemental fixation device via the lateral or anterior lateral surgical approach above the bifurcation of the great vessels or via the anterior surgical approach below the bifurcation of the great vessels. The Oro Plate System implants are manufactured from Ti-6Al-4V ELI per ASTM F136 with Nitinol springs per ASTM F2063 in the plate's screw anti-backout plates. The plates are offered in 1-Screw, 2-Screw, or 4-Screw configurations and in multiple lengths for single level fixation. The 1-Screw plate configuration is designed to maintain the relative position of interbody spacers during spinal fusion and is non-load bearing. The 2-Screw and 4-Screw plate configurations are designed as supplemental fixation for lumbar fusion. The plate screws are available in a variety of size options.

All Oro plates may be permanently attached to the F3D or CL5 spacers and assume the indications for use of the spacers.

The spacer and plate systems have been previously cleared (K183239, K150847, and K190016). This 510(k) submission offers additional implants to the previously cleared sets.

INDICATIONS FOR USE

The F3D Lateral Lumbar Interbody System is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). F3D Lateral Lumbar implants are to be used with autogenous bone graft and

supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

Hyperlordotic interbody devices (≥20° lordosis) must be used in conjunction with the Oro Lateral plate for fixation. If using the 1-hole CoreLink Oro Lateral Plate System, additional supplemental fixation is required (e.g. posterior fixation).

The CL5 Lumbar Cage is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). CL5 Lumbar implants are to be used with autogenous bone graft and supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

The CoreLink Oro Lateral Plate System (LPS), in two and four-hoe configurations, 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 Oro Lateral Plate System 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, pseudarthrosis, and failed previous fusion.

Alternatively, the CoreLink Oro Lateral Plate System may remain attached to CoreLink Lateral lumbar interbody devices after implantation. In this configuration the CoreLink Oro 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.

The CoreLink Oro LPS, one-hole configuration is intended for use in conjunction with traditional supplemental fixation to maintain the relative position of interbody spacers during spinal fusion. The one-hole plate is not intended for use in load-bearing applications.

Hyperlordotic interbody devices (≥20° lordosis) must be used in conjunction with the CoreLink Oro Lateral Plate System (LPS) for fixation.

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. Specifically, the following characteristics are the same between the subject and predicates:

- Indications for Use
- Materials of manufacture
- Principles of Operation
- Structural support mechanism
- Implant Types & Styles
- Sizes
- Sterility
- Manufacturing and Biocompatibility
- Mechanical Performance

Predicate Devices

510k Number	Trade or Proprietary or Model Name	Manufacturer	Product Code	Predicate Type
K192006	SIRION Lateral Lumbar Interbody System	Astura Medical, LLC	MAX, KWQ, OVD	Primary
K202495	SIRION Lateral Lumbar Interbody Fusion	Astura Medical, LLC	MAX, OVD	Additional
K183239	CoreLink F3D™ Lateral System	CoreLink, LLC	MAX	Additional
K150847	Foundation™ Interbody Devices	CoreLink, LLC	ODP, MAX	Additional
K190016	Lateral Plate System	CoreLink, LLC	KWQ	Additional

PERFORMANCE DATA

The F3D Lateral Lumbar Interbody System, CL5 Lateral Lumbar Interbody System, and Oro Lateral Plate System have been tested in the following test modes:

- Expulsion
- Static Compression Bending per ASTM F1717
- Static Torsion per ASTM F1717
- Dynamic Compression Bending per ASTM F1717
- Static Cantilever Bending

The results of this non-clinical testing show that the strength of the F3D Lateral Lumbar Interbody System, CL5 Lateral Lumbar Interbody System, and Oro Lateral Plate System are sufficient for their intended use and are substantially equivalent to legally marketed predicate devices.

CONCLUSION

The overall technology characteristics and mechanical performance data lead to the conclusion that the F3D Lateral Lumbar Interbody System, CL5 Lateral Lumbar Interbody System, and Oro Lateral Plate System are substantially equivalent to the predicate device.