February 4, 2022

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

Re: K211417
Trade/Device Name: F3D-C2 Cervical Stand-Alone System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVE
Dated: December 30, 2021
Received: January 5, 2022

Dear Mr. 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,

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.

510(k) Number *(if known)*
K211417

Device Name
F3D-C2 Cervical Stand-Alone System

Indications for Use *(Describe)*

The F3D-C2 Cervical Stand-Alone System is a Stand-Alone anterior cervical interbody fusion system indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one or two contiguous disc levels depending on the assembly. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. The F3D-C2 Cervical Stand-Alone System is used to facilitate intervertebral body fusion in the cervical spine and is placed via an anterior approach at one- or two-disc levels (C2-T1) depending on the assembly. The interior of the spacers can be packed with autograft or allogenic bone graft comprising cancellous and/or corticocancellous bone graft and/or demineralized allograft bone with bone marrow aspirate as an adjunct to fusion. Patients should have at least six (6) weeks of non-operative treatment prior to treatment.

The F3D-C2 Cervical Stand-Alone System is an interbody fusion device intended to be used with two titanium alloy screws and/or anchors which accompany the implants. When used with screws, the F3D-C2 Cervical Stand-Alone System is intended for use at one or two levels of the cervical spine (C2-T1) and requires no additional fixation. When used with one or more anchors, the F3D-C2 Cervical Stand-Alone System is intended for use at one level of the cervical spine (C2-T1) and requires additional supplemental fixation such as posterior cervical screw fixation.

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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K211417 510(K) SUMMARY

Submitter's Name:	CoreLink, LLC
Submitter's Address:	2072 Fenton Logistics Park St. Louis, MO 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:	May 6, 2021
Trade or Proprietary Name:	F3D-C2 Cervical Stand-Alone System
Common or Usual Name:	Intervertebral Fusion Device with Integrated Fixation, Cervical
Classification:	Class II per 21 CFR §888.3080
Product Code:	OVE
Classification Panel:	Orthopedic

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The CoreLink F3D Cervical Stand-Alone Interbody Fusion System is a collection of additively manufactured and machined implants and associated instruments for surgical site preparation and implantation to provide mechanical support to the cervical spine while arthrodesis occurs. The subject cages are additively manufactured from Ti-6Al-4V per ASTM F3001. Integration consists of additive Ti-6Al-4V (ASTM F3001) anchors (also referred to as nails) or machined Ti-6A-4V (ASTM F136 and ISO 5832-3) screws. The spacer and screw components are available in an assortment of dimensional combinations to accommodate the individual anatomic and clinical circumstances of each patient. The basic shape of the spacer is a trapezoidal column to provide surgical stabilization of the spine. The inferior/superior aspects of the spacer incorporate a vertical cavity which can be packed with bone graft.

INDICATIONS FOR USE

The F3D-C2 Cervical Stand-Alone System is a Stand-Alone anterior cervical interbody fusion system indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one or two contiguous disc levels depending on the assembly. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. The F3D-C2 Cervical Stand-Alone System is used to facilitate intervertebral body fusion in the cervical spine and is placed via an anterior approach at one- or two-disc levels (C2-T1) depending on the assembly. The interior of the spacers can be packed with autograft or allogenic bone graft comprising cancellous and/or corticocancellous bone graft and/or demineralized allograft bone with bone marrow aspirate as an adjunct to fusion. Patients should have at least six (6) weeks of non-operative treatment prior to treatment.

The F3D-C2 Cervical Stand-Alone System is an interbody fusion device intended to be used with two titanium alloy screws and/or anchors which accompany the implants. When used with screws, the F3D-C2 Cervical Stand-Alone System is intended for use at one or two levels of the cervical spine (C2-T1) and requires no additional fixation. When used with one or more anchors, the F3D-C2 Cervical Stand-Alone System is intended for use at one level of the cervical spine (C2-T1) and requires additional supplemental fixation such as posterior cervical screw 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 identical between the subject and predicates:

- Indications for Use
- Materials of manufacture
- Sizes
- Biocompatibility
- Mechanical Performance

Table 5-1 Predicate Devices

510k Number	**Trade or Proprietary or Model Name**	**Manufacturer**	**Predicate Type**
K200087	F3D Cervical Stand-Alone Interbody Fixation System	CoreLink, LLC	Primary
K173115	MIS COALITION® Spacers	Globus Medical	Additional
K152793	Unison-C Anterior Cervical Fixation System	RTI Surgical, Inc.	Additional
K191489	Genesys Spine 3DP Cervical Interbody System	Genesys Spine	Additional

PERFORMANCE DATA

The F3D-C2 Cervical Stand-Alone System has been tested in the following test modes:

- Static axial compression per ASTM F2077
- Static compression shear per ASTM F2077
- Static torsion per ASTM F2077
- Dynamic axial compression per ASTM F2077
- Dynamic compression shear per ASTM F2077
- Dynamic torsion per ASTM F2077
- Subsidence per ASTM F2267
- Expulsion
- Pullout per ASTM F543

- Static cantilever bending per ASTM F2193
- Dynamic cantilever bending per ASTM F2193
- Anchor backout

The results of this non-clinical testing show that the performance of the F3D-C2 Cervical Stand-Alone 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 F3D-C2 Cervical Stand-Alone System is substantially equivalent to the predicate device.