DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 4, 2017

CoreLink, LLC
℅ Mr. Kenneth Maxwell
Regulatory and Quality Specialist
Empirical Testing Corp.
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K162496
Trade/Device Name: Foundation™ 3D Interbody
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP, MAX
Dated: March 31, 2017
Received: April 3, 2017

Dear Mr. Maxwell:

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. 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162496

Device Name
Foundation™ 3D Interbody

Indications for Use *(Describe)*
The Foundation™ 3D Interbody Cervical Cage is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. Foundation™ Cervical implants are used to facilitate intervertebral body fusion in the cervical spine and are placed via an anterior approach at one disc level (C2-T1) using autograft bone. Foundation™ 3D Interbody implants are to be used with supplemental fixation. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

The Foundation™ 3D Interbody 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). Foundation™ 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.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) SUMMARY

Submitter's Name:	CoreLink, LLC
Submitter's Address:	7911 Forsyth Blvd , Suite #200 St. Louis, MO 63105
Submitter's Telephone:	888.349-7808
Contact Person:	Kenneth C. Maxwell II Empirical Testing Corp. 719.291.6874
Date Summary was Prepared:	31 March 2017
Trade or Proprietary Name:	Foundation™ 3D Interbody
Common or Usual Name:	Intervertebral Fusion Device With Bone Graft, Cervical Intervertebral Fusion Device With Bone Graft, Lumbar
Classification:	Class II per 21 CFR §888.3080
Product Code:	ODP, MAX
Classification Panel:	Division of Orthopedic Devices

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Foundation™ 3D Interbody Cervical Series Interbody System is an additively manufactured implant comprising of cervical interbody spacers. They are designed to provide mechanical support to the cervical spine while arthrodesis occurs. The cervical line has a partially porous construction and an open architecture with a large variety of footprints and lordosis angles to help optimize implant fit.

The Foundation™ 3D Interbody Lumbar Series Interbody System is an additively manufactured implant comprising of lumbar interbody spacers. They are designed to provide mechanical support to the lumbar spine while arthrodesis occurs. The lumbar lines feature a wide variety of lordosis and footprint options with fully porous architectures and varying pore sizes to offer increased room for bone growth with mechanical stability.

The Foundation™ 3D series of intervertebral body fusion devices are made from the titanium alloy Ti-6AL-4V ELI conforming to the ASTM F-136 specifications.

INDICATIONS FOR USE

The Foundation™ 3D Interbody Cervical Cage is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. Foundation™ Cervical implants are used to facilitate intervertebral body fusion in the cervical spine and are placed via an anterior approach at one disc level (C2-T1) using autograft bone. Foundation™ 3D Interbody implants

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

The Foundation™ 3D Interbody 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). Foundation™ 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 indications for use for the Foundation™ 3D Interbody is similar to that of the predicate devices listed in Table 5-1 below.

Table 5-1: Predicate Devices

510k Number	**Trade or Proprietary or Model Name**	**Manufacturer**	**Predicate Type**
K150847 K073440	Foundation™ Interbody System	CoreLink	Primary
K151322	Interbody Fusion Device	Amendia	Additional
K120486	AVS AS System	Striker Spine	Additional
K153250	Tesera SC Stand-alone Anterior Cervical Fusion (ACF) System	Renovis	Reference
K150765 K121103 K113559	ROI-C	LDR	Reference
K112095 K123281 K123752	AccuLiF® TL-PEEK Cage and AccuLiF® TL and PL	CoAlign Innovation	Reference

PERFORMANCE DATA

The Foundation™ 3D Interbody has been tested in the following test modes:

- Static axial compression per ASTM F2077
- Static torsion per modified ASTM F2077
- Static compressive shear per ASTM F2077
- Dynamic axial compression per ASTM F2077
- Dynamic torsion per ASTM F2077
- Dynamic compressive shear per ASTM F2077
- Subsidence per ASTM F2267
- Expulsion per ASTM F-04.25.02.02 DRAFT

The results of this non-clinical testing show that the strength of the Foundation™ 3D Interbody is sufficient for its intended use and is substantially equivalent to legally marketed predicate devices.

TECHNOLOGICAL CHARACTERISTICS

The following characteristics are similar between the subject and predicate devices:

- Principles of Operations
- Indications for Use
- Materials
- Sterility

CONCLUSION

The overall technology characteristics and mechanical performance data lead to the conclusion that the Foundation™ 3D Interbody is substantially equivalent to the predicate device.