Corelink, LLC
% Vikki M. O'Connor
Regulatory Affairs Consultant
Ambriel Associates, Inc.
411 Walnut St. Unit 9236
Green Cove Springs, Florida 32043

July 27, 2018

Re: K180556
Trade/Device Name: Corelink Foundation 3D Anterior Lumbar System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: June 8, 2018
Received: June 29, 2018

Dear Vikki M. O'Connor:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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

for
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180556

Device Name
Corelink Foundation 3D Anterior Lumbar System

Indications for Use *(Describe)*
Foundation 3D cervical implants are 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.

Foundation 3D lumbar implants are 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 nonoperative 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.

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510(k) Summary: Corelink Foundation 3D Anterior Lumbar System

In accordance with Title 21 of the Code of Federal Regulations, Part 807, and in particular, 21 CFR Part 807.92, the following summary of information is provided:

Submitter:	Corelink, LLC 7911 Forsyth Blvd. Suite #200 St. Louis, MO 63105
Contact Person	Ms. Vikki M. O'Connor Regulatory Affairs Consultant Phone: 1-207-214-8535 Email: vikki0730@yahoo.com
Date Prepared	June 8, 2018
Trade Name	Corelink Foundation 3D Anterior Lumbar System
Proposed Class	Class II
Classification Name and Number	Intervertebral Fusion Device with Bone Graft, Lumbar 888.3080
Common Name	Interbody Fusion Device
Product Code / Panel	MAX / Orthopedics
Predicate Device	Corelink Foundation 3D Interbody – K162496 (Primary Predicate), Corelink Foundation Lumbar Interbody Devices - K150847
Special Controls	N/A
Purpose of Submission	To add additional Anterior Lumbar Interbody Cage footprints / sizes to the existing system.
Device Description	The Foundation 3D Anterior Lumbar System is intended to be used as interbody fusion devices. The Foundation 3D Anterior Lumbar System consists of additively manufactured interbody cages, re-usable instruments and a sterilization tray.

	Foundation 3D Anterior Lumbar Cages are inserted between vertebral bodies in the anterior column of the lumbar spine. The new footprint / size cages are for this lumbar indication. The cages are designed to provide mechanical support to the lumbar spine while arthrodesis occurs. The lumbar line features 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 Anterior Lumbar System cages are made from the Titanium alloy Ti-6AL-4V ELI (conforming to ASTM F136 in terms of mechanical properties only) and are open in the center to accept autogenous bone graft material. The new Anterior Lumbar Cages, which are the subject of this 510k, are in sizes: 25mm x 35mm, 25mm x 40mm, 27mm x 35mm, 27mm x 40mm, 30mm x 40mm, and 30mm x 45mm. Each footprint offers cage heights ranging from 10mm to 21mm in 1mm increments along with lordosis angles of 8° and 15°.
Indications for Use	The Foundation 3D cervical implants are 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 lumbar implants are 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.
Summary of the Technological Characteristics	Foundation 3D Anterior Lumbar System cages possess the same technological characteristics as the primary predicate Foundation 3D Interbody Lumbar Cages (K162496). These include: Indications for Use, Method of manufacture, implant design, materials, method of implantation, method of packaging and sterilization. The new sizes do not add additional risks and do not represent a new worst case.
Performance Data	Based on the risk analysis for the new implant sizes and deign verification testing conducted on the Foundation 3D Anterior Lumbar Cages, including Finite Element Analysis (FEA), it was determined that inclusion of these new sizes into the Foundation 3D Interbody System do not create a

	new worst-case test condition for mechanical testing, performance testing, sterilization, biocompatibility, shelf life, cleaning or packaging. Therefore, in accordance with the design control process, additional performance data was not necessary for the changes subject of this Special 510(k).
Difference between Subject and Predicate	The only difference between the subject and predicate devices are the addition of new lumbar sizes.
Conclusion	Based on the indications for use, technological characteristics, materials, required performance testing, principles of operation, anatomical site, safety characteristics and comparison to the predicate device, Corelink's Foundation 3D Interbody Anterior Lumbar Cages have been shown to be substantially equivalent to the legally marketed predicate device.