DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 13, 2015

CoreLink, LLC
% Mr. J.D. Webb
Official Correspondent
The Orthomedix Group, Incorporated
1001 Oakwood Boulevard
Round Rock, Texas 78681

Re: K150847
Trade/Device Name: Foundation™ Interbody Devices
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP, MAX
Dated: June 22, 2015
Received: July 27, 2015

Dear Mr. Webb:

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" (21CFR 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 yours,

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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

K150847

Device Name

Foundation™ Interbody Devices

Indications for Use *(Describe)*

Foundation™ Cervical Interbody Devices 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 Cervical 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™ Lumbar Interbody Devices 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™ 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.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

*5*10(k) Summary: Foundation™ Interbody Devices

Date Prepared	March 26, 2015
Submitted By	Corelink, LLC 7606 Forsyth Blvd Clayton, MO 63105 888-349-7808 Tele
Contact	J.D. Webb 1001 Oakwood Blvd Round Rock, TX 78681 512-388-0199 Tele 512-692-3699 Fax e-mail: jdwebb@orthomedix.net
Trade Name	Foundation™ Interbody Devices
Common Name	intervertebral body fusion device
Classification Name	intervertebral body fusion device - cervical intervertebral body fusion device - lumbar
Class	II
Product Code	ODP MAX
CFR Section	21 CFR section 888.3080
Device Panel	Orthopedic
Primary Predicate Device	Foundation™ Interbody Devices - K073440
Secondary Predicate Devices	Amendia (Verticor) Zeus Cage - K081614 DePuy Bengal - K081917 Medtronic Verte-Stack Crescent - K094025, K133216 Lanx Timberline - K073144 Eminent Spine Cottonmouth - K090064 Tyber Medical PLIF - K130573
Device Description	The Foundation™ Interbody Devices are implants developed for the substitution of the classical autogenous bone graft blocks. The cages assist to avoid complications related to the graft donation site. They are available in a range of footprints and heights to suit the individual pathology and anatomical conditions of the patient. The implants have a hollow center to allow placement of autogenous bone graft. The superior and inferior surfaces are open to promote contact of the bone graft with the vertebral end plates, allowing bone growth (arthrodesis). The changes to the Foundation™ Interbody Devices cleared in K0733440 and included in this Special 510(k) are: • Removal of specific surgical approaches for the lumbar devices • Addition of additional sizes and configurations

Materials	Invibio® PEEK Optima LT1 (ASTM F2026) Tantalum (ASTM F560).
Substantial Equivalence Claimed to Predicate Devices	The Foundation™ Interbody Devices are substantially equivalent to the predicate devices in terms of intended use, design, materials used, mechanical safety and performances.
Indications for Use	Foundation™ Cervical Interbody Devices 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™ Cervical 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™ Lumbar Interbody Devices 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™ 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.
Non-clinical Test Summary	The following analyses were conducted: • Finite Element Analysis • Bone graft area in contact with endplates and graft volume • Cross sectional area The results of these evaluations indicate that the Foundation™ Interbody Devices are equivalent to predicate devices.
Clinical Test Summary	No clinical studies were performed
Conclusions: Non-clinical and Clinical	Corelink, LLC considers the Foundation™ Interbody Devices to be equivalent to the predicate devices listed above. This conclusion is based upon the devices' similarities in principles of operation, technology, materials and indications for use