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

February 4, 2016

CoreLink, LLC
% Kenneth Maxwell II
Regulatory and Quality Specialist
Empirical Testing Corporation
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K152237
Trade/Device Name: The Entasis™ Dual-Lead Sacroiliac Implant
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: OUR
Dated: December 31, 2015
Received: January 4, 2015

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 Parts 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,

Lori A. Wiggins -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: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K152237

Device Name
Entasis™ Dual-Lead Sacroiliac Implant

Indications for Use *(Describe)*

The Entasis™ Dual-Lead Sacroiliac Implant system is intended for sacroiliac joint fusion for conditions including degenerative sacroilitis and sacroiliac joint disruptions.

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)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.
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5. 510(K) SUMMARY

Submitter's Name:	CoreLink, LLC
Submitter's Address:	7606 Forsyth Blvd 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:	04 February 2016
Trade or Proprietary Name:	Entasis™ Dual-Lead Sacroiliac Implant
Common or Usual Name:	Smooth or threaded metallic bone fixation fastener
Classification:	Class II per 21 CFR §888.3040 Device Classification
Product Code:	OUR
Classification Panel:	Division of Orthopedic Devices

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION

The Entasis™ Dual-Lead Sacroiliac Implant system is composed of dual-lead sacroiliac screws manufactured from titanium (Ti-6Al-4V ELI) per ASTM F136. The screws are available in lengths of 30-70mm and diameters of 7-11.5mm.

INDICATIONS FOR USE

The Entasis™ Dual-Lead Sacroiliac Implant system is intended for sacroiliac joint fusion for conditions including degenerative sacroilitis and sacroiliac joint disruptions.

The indications for use for the CoreLink, LLC Entasis™ Dual-Lead Sacroiliac Implant is similar to that of the predicates listed in Table 5-1 Predicate Devices.

TECHNOLOGICAL CHARACTERISTICS

The subject and predicate devices have similar technological characteristics and the minor differences do not raise any new issues of safety and effectiveness. The following characteristics are similar between the subject and predicate devices:

- Indications for Use
- Materials of Manufacture
- Principles of Operation

Table 5-1: Predicate Devices

510k Number	**Trade or Proprietary or Model Name**	**Manufacturer**	**Predicate Type**
K021932	6.5mm Cannulated Screw	Synthes	Primary
K140079	Silex	X-spine	Additional

PERFORMANCE DATA

The Entasis™ Dual-Lead Sacroiliac Implant has been tested in the following test modes:

- Static torsion per ASTM F543
- Static pullout per ASTM F543
- Static driving torque per ASTM F543
- Static three-point bending per ASTM F2193
- Dynamic three-point bending per ASTM F2193

The results of this non-clinical testing show that the strength of the Entasis™ Dual-Lead Sacroiliac Implant 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 Entasis™ Dual-Lead Sacroiliac Implant is substantially equivalent to the predicate device.