March 21, 2023

CoreLink, LLC
Nathan Wright
Engineer & Regulatory Specialist
Empirical Technologies
4628 Northpark Dr.
Colorado Springs, Colorado 80918

Re: K223708
Trade/Device Name: Entasis 3D Dual-Lead Sacroiliac Implant System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: OUR, HWC
Dated: December 9, 2022
Received: December 12, 2022

Dear Nathan 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,

Colin O'neill -S

Colin O'Neill, MBE
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)*
K223708

Device Name
Entasis 3D Dual-Lead Sacroiliac Implant System

Indications for Use *(Describe)*
The Entasis 3D Dual-Lead Sacroiliac Implant System is intended for sacroiliac joint fusion for conditions including degenerative sacroiliitis and sacroiliac joint disruptions, to augment immobilization and stabilization of the sacroiliac joint in skeletally mature patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion and acute, non-acute, and non-traumatic fractures involving the sacroiliac joint. This includes those whose symptoms began during pregnancy or in the peripartum period and have persisted postpartum for more than 6 months.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K223708 – 510(K) SUMMARY

Submitter's Name:	CoreLink, LLC
Submitter's Address:	2072 Fenton Logistics Park St. Louis, Missouri 63026
Submitter's Telephone:	888-349-7808
Contact Person:	Nathan Wright MS Empirical Technologies 1-719-351-0248 nwright@empiricaltech.com
Date Summary was Prepared:	December 9, 2022
Trade or Proprietary Name:	Entasis 3D Dual-Lead Sacroiliac Implant System
Device Classification Name:	Sacroiliac Joint Fixation
Classification & Regulation #:	Class II per 21 CFR §888.3040
Product Code:	OUR, HWC
Classification Panel:	Orthopedic Devices – Spinal Devices (DHT6B)

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Entasis 3D Dual-Lead Sacroiliac Implant System consists of additive and machined dual-lead sacroiliac screws and optional washers to aid in load bearing and conformity to patient anatomy. The Entasis 3D Dual-Lead Sacroiliac Implant System is manufactured from additive titanium alloy (Ti-6Al-4V) per ASTM F3001 or machined from titanium alloy (Ti-6Al-4V ELI) per ASTM F136. These screws are available in lengths from 30 mm to 110 mm and diameters of Ø7 mm to Ø14.5 mm.

INDICATIONS FOR USE

The Entasis 3D Dual-Lead Sacroiliac Implant System is intended for sacroiliac joint fusion for conditions including degenerative sacroiliitis and sacroiliac joint disruptions, to augment immobilization and stabilization of the sacroiliac joint in skeletally mature patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion and acute, non-acute, and non-traumatic fractures involving the sacroiliac joint. This includes those whose symptoms began during pregnancy or in the peripartum period and have persisted postpartum for more than 6 months.

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 subject shares the following same characteristics as the predicates:

- Indications for Use
- Materials of Manufacturer
- Structural Support Mechanism
- Surgical Approach
- Sizes and Design Features

Predicate Devices

510k Number	Trade or Proprietary or Model Name	Manufacturer	Product Code	Predicate Type
K212903	SIMPACT Sacroiliac Joint Fixation System	Life Spine, Inc.	OUR, HWC	Primary
K222605	iFuse TORQ Implant System	SI-Bone, Inc.	OUR, HWC, OLO	Additional
K152237	Entasis Dual-Lead Sacroiliac Implant System	CoreLink, LLC	OUR	Additional
K220195	iFuse Bedrock Granite Implant System	SI-Bone, Inc.	OUR, NKB, OLO	Additional

PERFORMANCE DATA

The Entasis 3D Dual-Lead Sacroiliac Implant System has been tested in the following test modes:

- Static Torsion per ASMT F3574
- Driving Torsion per ASTM F3574
- Pullout per ASTM F3574
- Static & Dynamic Cantilever Bending per ASTM F3547

The results of this non-clinical testing show that the strength of the Entasis 3D Dual-Lead Sacroiliac Implant 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 Entasis 3D Dual-Lead Sacroiliac Implant System is substantially equivalent to the predicate device.