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

June 21, 2017

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

Re: K163104
Trade/Device Name: Terrace™ Anterior Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: June 12, 2017
Received: June 13, 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)*
K163104

Device Name

Terrace™ Anterior Cervical Plate System

Indications for Use *(Describe)*

The CoreLink TERRACE™ Anterior Cervical Plate System is intended for anterior fixation of the cervical spine. Indications for use include the temporary stabilization of the anterior spine during the evolution of cervical fusions in patients with degenerative disc disease (DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.), trauma (including fractures), tumors, deformity (defined as kyphosis, lordosis, or scoliosis), pseudarthrosis, and/or failed previous fusions. The intended levels for treatment range from C2 – T1.

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."

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:	20 June 2017
Trade or Proprietary Name:	Terrace™ Anterior Cervical Plate System
Common or Usual Name:	Appliance, Fixation, Spinal Intervertebral Body
Classification:	Class II per 21 CFR §888.3060 Device Classification
Product Code:	KWQ
Classification Panel:	Division of Orthopedic Devices

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Terrace™ Anterior Cervical Plate System is indicated for one through five levels of fixation and are provided in multiple sizes to accommodate a variety of patient anatomies. Screws are provided in multiple sizes to accommodate a variety of patient anatomies. Implants are manufactured from Ti-6Al-4V ELI conforming to ASTM F136 and nitinol conforming to ASTM F2063. Implants are provided non-sterile with instructions for sterilization.

INDICATIONS FOR USE

The CoreLink TERRACE™ Anterior Cervical Plate System is intended for anterior fixation of the cervical spine. Indications for use include the temporary stabilization of the anterior spine during the evolution of cervical fusions in patients with degenerative disc disease (DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.), trauma (including fractures), tumors, deformity (defined as kyphosis, lordosis, or scoliosis), pseudarthrosis, and/or failed previous fusions. The intended levels for treatment range from C2 – T1.

The indications for use for the Terrace™ Anterior Cervical Plate System is similar to that of the predicate devices noted in Table 5-1.

Table 5-1 Predicate Devices

510k Number	**Trade or Proprietary or Model Name**	**Manufacturer**	**Predicate Type**
K121514	ANODYNE® ACP System	CoreLink, LLC	Primary
K102820	Trestle Luxe ACP	Alphatec	Additional
K100614	Anterior Cervical Plating System	Orthofix	Additional
K130202	IRIS™ ACP	Life Spine	Additional
K133475	Struxxure	Next Spine	Additional

PERFORMANCE DATA

The Terrace™ Anterior Cervical Plate System has been tested in the following test modes:

- Static axial compression bending per ASTM F1717-14
- Static torsion per ASTM F1717-14
- Dynamic axial compression bending fatigue per ASTM F1717-14
- Corrosion testing per ASTM F2129

The results of this non-clinical testing show that the strength of the Terrace™ Anterior Cervical Plate System 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 Terrace™ Anterior Cervical Plate System is substantially equivalent to the predicate device.