CoreLink, LLC
% Meredith L. May
Vice President
Empirical Consulting, LLC
4628 Northpark Drive
Colorado Springs, Colorado 80918

August 10, 2018

Re: K180814
Trade/Device Name: CoreLink® M3™ Stand-Alone Anterior Lumbar System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVD
Dated: July 5, 2018
Received: July 10, 2018

Dear Meredith L. May:

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)*
K180814

Device Name
CoreLink® M3™ Stand-Alone Anterior Lumbar System

Indications for Use *(Describe)*
The CoreLink® M3™ Stand-Alone Anterior Lumbar System is a standalone interbody fusion system indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). The device may be used with supplemental fixation.

Hyperlordotic implants (>20° lordosis) must be used with supplemental fixation (e.g. posterior fixation) that are cleared by the FDA for use in the lumbar spine. The system is indicated to be used with autograft bone. Patients should have received 6 months of non- operative treatment prior to treatment with the devices.

The implants are intended to be used with the bone screws and lock provided. The system is designed to be a 3-screw implant, and all three (3) screws must be used. The accompanying lock must be used anytime the device is used with any number of screws. If the physician chooses to use less than the recommended number, then additional supplemental fixation in the lumbar spine must be used to augment fixation.

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.

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:	Meredith L. May MS, RAC Empirical Consulting 719.337.7579
Date Summary was Prepared:	19-Mar-18
Trade or Proprietary Name:	CoreLink® M3™ Stand-Alone Anterior Lumbar System
Common or Usual Name:	Intervertebral Body Fusion Device
Classification:	Class II per 21 CFR §888.3080
Product Code:	OVD
Classification Panel:	Orthopedic Devices

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The CoreLink® M3™ Stand-Alone Anterior Lumbar System is available in a variety of different shapes and sizes to suit the individual pathology and anatomical conditions of the patient. The CoreLink® M3™ Stand-Alone Anterior Lumbar System consists of an interbody cage, locking plate, and three (3) bone screws. System components are manufactured from either titanium alloy (Ti-6Al-4V ELI) conforming to ASTM F136 and ISO 5832-3 or additively manufactured from titanium alloy (Ti-6Al-4V) conforming to ASTM F3001. The 8°, 15°, and 20° lordotic cages may be used as a standalone system. The M3 Stand-Alone Anterior Lumbar System M3 Stand-Alone Anterior Lumbar System 25° - 30° lordotic cages must be used with supplemental internal spinal fixation systems (i.e. posterior pedicle screw and rod system) that are cleared by the FDA for use in the lumbar spine.

INDICATIONS FOR USE

The CoreLink® M3™ Stand-Alone Anterior Lumbar System is a standalone interbody fusion system indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). The device may be used with supplemental fixation.

Hyperlordotic implants (>20° lordosis) must be used with supplemental fixation (e.g. posterior fixation) that are cleared by the FDA for use in the lumbar spine. The system is indicated to be used with autograft bone. Patients should have received 6 months of non-operative treatment prior to treatment with the devices.

The implants are intended to be used with the bone screws and lock provided. The system is designed to be a 3-screw implant, and all three (3) screws must be used. The accompanying lock must be used anytime the device is used with any number of screws. If the physician chooses to use less than the recommended number, then additional supplemental fixation in the lumbar spine must be used to augment fixation.

The indications for use for the CoreLink® M3™ Stand-Alone Anterior Lumbar System is similar to that of the NuVasive® ALIF Interfixated System.

TECHNOLOGICAL CHARACTERISTICS

Technical characteristics should include design, material, size, and shared similarities with predicate devices.

M3 Stand-Alone Anterior Lumbar System is made from material that conforms to ASTM F136 and ISO 5832-3. 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 following characteristics are identical between the subject and predicates:

- Indications for Use
- Materials of manufacture
- Structural support mechanism

Table 5-1 Predicate Devices

510k Number	**Trade or Proprietary or Model Name**	**Manufacturer**	**Predicate Type**
K151214	ALIF Interfixated System	NuVasive	Primary
K111626	Endoskeleton TAS	Titan Spine	Additional
K142095	Tesera SA ALIF Interbody System	Renovis Spine	Additional
K150847	CoreLink Lateral	CoreLink	Additional
K162496	Foundation™ 3D Interbody	CoreLink	Additional

PERFORMANCE DATA

The M3 Stand-Alone Anterior Lumbar System has been tested in the following test modes:

- Static axial compression per ASTM F2077-14
- Static compressive shear per ASTM F2077-14
- Static subsidence per ASTM F2267-04
- Static expulsion
- Dynamic axial compression per ASTM F2077-14
- Dynamic compressive shear per ASTM F2077-14
- Screw backout

- Wear debris analysis per ASTM F1877-16

The results of this non-clinical testing show that the strength of the M3 Stand-Alone Anterior Lumbar 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 CoreLink® M3™ Stand-Alone Anterior Lumbar System is substantially equivalent to the predicate device.