September 13, 2018

Life Spine, Inc.
Randy Lewis
General Manger
13951 S Quality Drive
Huntley, Illinois 60142

Re: K180215
Trade/Device Name: DYNA-LINK ELITE Stand-Alone Anterior Lumbar System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVD, MAX
Dated: August 14, 2018
Received: August 15, 2018

Dear Mr. Lewis:

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,

Melissa Hall -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 below.

510(k) Number *(if known)*
K180215

Device Name
DYNA-LINK ELITE Stand-Alone Anterior Lumbar System

Indications for Use *(Describe)*
The DYNA-LINK ELITE Stand-Alone Anterior Lumbar System is intended for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels (L2-S1). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. DDD patients may also have up to Grade 1 spondylolisthesis at the involved level(s). It is to be used in patients who have had at least six months of non-operative treatment. This device is intended to be used with autogenous bone graft.
The DYNA-LINK ELITE Stand-Alone Anterior Lumbar System is intended for use with four titanium alloy screws which are provided with the system. If the physician chooses to use fewer than four of the provided screws, then a supplemental internal spinal fixation system that is cleared for use in the lumbosacral spine must be used.

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.

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510(k) Summary
DYNA-LINK ELITE Stand-Alone Anterior Lumbar System

Submitted By: Life Spine, Inc.
13951 S. Quality Drive
Huntley, IL 60142
Telephone: 847-884-6117
Fax: 847-884-6118

510(k) Contact: Randy Lewis
Life Spine
13951 S. Quality Drive
Huntley, IL 60142
Telephone: 847-884-6117
Fax: 847-884-6118

Date Prepared: January 24th, 2018

Trade Name: DYNA-LINK ELITE Stand-Alone Anterior Lumbar System

Regulation Name: Intervertebral body fusion device

Classification: OVD, CFR 888.3030, Class II
MAX, CFR 888.3030, Class II

Primary Predicate: Life Spine Stand-Alone Space System (K091301)

Secondary Predicate: Centinel Spine Midline (K150643)

Device Description:
The DYNA-LINK Elite Stand-Alone Anterior Lumbar System implants are intervertebral body fusion devices comprised of a variety of spacer implants manufactured from Polyetheretherketone (PEEK-OPTIMA LT1 or Zeniva ZA-500) with tantalum markers. The spacers are hollow to permit packing with bone graft to help promote intervertebral body fusion. The superior and inferior surfaces have teeth to assist in the interface with the vertebral end plates to help prevent rotation and/or migration. Additionally, the implants incorporate a titanium alloy (6AL-4V-ELI per ASTM F-136) anterior fixation plate which has integrated screw holes to allow for placement of four titanium alloy screws that anchor the implant to the adjacent vertebrae. The implants are available in a range of sizes and footprints to suit the individual pathology and anatomical conditions of the patient.

All implant components are intended for single use only and should not be reused under any circumstances. **Do not use any of the DYNA-LINK Elite Stand-Alone Anterior Lumbar System components with components from any other system or manufacturer. The DYNA-LINK Elite Stand-Alone Anterior Lumbar System components should never be reused under any circumstances**

Indications for Use of the Device:
The DYNA-LINK Elite Stand-Alone Anterior Lumbar System is intended for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels (L2-S1). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. DDD patients may also have up to Grade 1 spondylolisthesis at the involved level(s). It is to be used in patients who have had at least six months of non-operative treatment. This device is intended to be used with autogenous bone graft. The DYNA-LINK Elite Stand-Alone Anterior Lumbar System is intended for use with four titanium alloy screws which are provided with the system. If the physician chooses to use fewer than four of the provided screws, then a supplemental internal spinal fixation system that is cleared for use in the lumbosacral spine must be used.

Technological Characteristics:
The DYNA-LINK Elite Stand-Alone Anterior Lumbar System is substantially equivalent to the predicate system in terms of design, indications for use and sizing.

Material:
The DYNA-LINK Elite Stand-Alone Anterior Lumbar System is comprised of Peek and Titanium. The implant is Polyetheretherketone (PEEK-OPTIMA LT1 or Zeniva ZA-500) & Titanium alloy (6AL-4V-ELI) manufactured according to ASTM F2026-02 &ASTM F136-02a. The implant device is non-sterile and is a single use component.

Performance Data:
Mechanical testing according to ASTM F1717-04 including Static and Dynamic Compression, Shear, Torsion and also Screw Pushout to ASTM F543. Testing was presented to demonstrate the substantial equivalency of the DYNA-LINK Elite Stand-Alone Anterior Lumbar System.

Conclusion:
The information presented demonstrates the substantial equivalency of the DYNA-LINK Elite Stand-Alone Anterior Lumbar System.