May 10, 2018

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

Re: K180642
Trade/Device Name: Pro-Link® Ti Stand-Alone Cervical Spacer System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVE
Dated: March 7, 2018
Received: March 12, 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. 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.

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.

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,

Katherine D. Kavlock -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)*
K180642

Device Name
Pro-Link® Ti Stand-Alone Cervical Spacer System

Indications for Use *(Describe)*
The Pro-Link® Ti Stand-Alone Cervical Spacer System is intended to be used with the screws provided and requires no additional supplementary fixation.
The Pro-Link® Ti Stand-Alone Cervical Spacer System is intended for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one disc level (C2-T1). DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. It is to be used in patients who have had at least six weeks of non-operative treatment. This device is intended to be used with autogenous bone graft.

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
Life Spine Pro-Link® Ti Stand-Alone Cervical Spacer

Submitted By: Life Spine, Inc.
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510(k) Contact: Randy Lewis
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Telephone: 847-884-6117
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Date Prepared: April 23rd, 2018

Trade Name: Pro-Link® Ti Stand-Alone Cervical Spacer

Common Name: Intervertebral body fusion device

Classification: OVE, 21 CFR 888.3080, Class II

Primary Predicate: Life Spine PRO-LINK Spacer System (K121151)

Additional Predicates: Life Spine PRO-LINK TITANIUM Spacer System (K160066)
Life Spine Plateau-C Titanium (K161127)
DePuy Synthes Bengal Cervical Interbody System (K081917)

Device Description:

The Pro-Link® Ti Stand-Alone Cervical Spacer System is intended to serve as an intervertebral body fusion device. The implant is available in a range of sizes and footprints to suit the individual pathology and anatomical conditions of the patient. It is fabricated and manufactured from titanium (Ti 6Al-4V ELI). The implant is hollow to permit packing with autogenous bone graft to help promote intervertebral body fusion. The superior and inferior surfaces have teeth to assist in the interface with the vertebral endplates to prevent rotation and/or migration. The implant has two pockets to permit placement of titanium bone screws (Ti 6Al-4V ELI) through the interbody to provide internal fixation. The implant also has one central threaded hole to permit the insertion of a titanium lock plate (Ti 6Al-4V ELI) to prevent screw back out.

All implants are intended for single use only and should not be reused under any circumstances. Do not use any of the Pro-Link Ti Stand-Alone Cervical Spacer System components with components from any other system or manufacturer. The PRO-LINK Ti Stand-Alone Cervical Spacer System components should never be reused under any circumstances.

Indications for Use:

The Pro-Link® Ti Stand-Alone Cervical Spacer System is intended to be used with the screws provided and requires no additional supplementary fixation.
The Pro-Link® Ti Stand-Alone Cervical Spacer System is intended for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one-disc level (C2-T1). DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. It is to be used in patients who have had at least six weeks of non-operative treatment. This device is intended to be used with autogenous bone graft.

Technological Characteristics:

The Life Spine Pro-Link® Ti Stand-Alone Cervical Spacer System is substantially equivalent to the predicate systems in terms of design, materials, indications for use and sizing.

Material:

This submission seeks clearance of a device made from implant grade (Ti-6AL-4V) Titanium alloy according to F136. This is the same material used in the predicate devices.

Performance Data:

Engineering rationales and FEA were provided to demonstrate the substantial equivalency of the Life Spine PRO-LINK Ti Stand-Alone Cervical Spacer System.

Substantial Equivalence:

The Life Spine Pro-Link® Ti Stand-Alone Cervical Spacer System was shown to be substantially equivalent to the predicate devices in indications for use, design, function, materials used and mechanical performance.

Conclusion:

The information presented demonstrates the substantial equivalency of the Life Spine Pro-Link® Ti Stand-Alone Cervical Spacer System.