October 19, 2023

Life Spine, Inc.
Angela Batker
RA/QA Manager
13951 S. Quality Drive
Huntley, Illinois 60142

Re: K231704
Trade/Device Name: Pro-Link® & Pro-Link® Ti Barbs Cervical Spacer System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVE
Dated: October 11, 2023
Received: October 11, 2023

Dear Angela Batker:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Katherine D. Kavlock -S

for
Brent Showalter, Ph.D.
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K231704

Device Name

Pro-Link® & Pro-Link® Ti Barbs Cervical Spacer System

Indications for Use *(Describe)*

The Pro-Link® & Pro-Link® Ti Barbs Cervical Spacer System is an anterior cervical interbody fusion device indicated for use in skeletally mature patients with degenerative disc disease (DDD) with accompanying radicular symptoms at one level from C2-T1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six weeks of non-operative treatment. The Pro-Link® & Pro-Link® Ti Barbs Cervical Spacer System is to be used with autogenous bone graft and implanted via an anterior approach.

The Pro-Link® & Pro-Link® Ti Barbs Cervical Spacer System is an integrated cervical interbody fusion device intended to be used with two (2) titanium bone barbs. The Pro-Link® & Pro-Link® Ti Barbs Cervical Spacer System must be used with supplemental fixation (e.g., anterior plate, posterior cervical screw).

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
Pro-Link® & Pro-Link® Ti Barbs Cervical Spacer System

Submitted By: Life Spine, Inc.
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510(k) Contact: Angela Batker
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Date Prepared: October 11th, 2023

Trade Name: Pro-Link® & Pro-Link® Ti Barbs Cervical Spacer System

Common Name: Intervertebral Body Fusion Device

Classification: OVE, 21 CFR 888.3080, Class II

Primary Predicate: Life Spine Pro-Link Stand-Alone Cervical Spacer System (K121151)

Additional Predicate: Life Spine Pro-Link TI Stand-Alone Cervical Spacer System (K180642 & K160066)
Genesys Spine AIS-C (K181295)

Device Description:

The Pro-Link® & Pro-Link® Ti Barbs Cervical Spacer System is offered in various device configurations based on surgical approach and patient anatomy. The Pro-Link® & Pro-Link® Ti Barbs Cervical Spacer System includes an interbody, containing a titanium alloy locking mechanism, which is implanted with two (2) titanium bone barbs. The interbody is offered in either PEEK (Polyetheretherketone) or in titanium alloy (Ti 6Al-4V ELI). The Pro-Link® & Pro-Link® Ti Barbs Cervical Spacer System must be used with supplemental fixation (e.g., anterior plate, posterior cervical screws).

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

Intended Use of the Device:
The Pro-Link® & Pro-Link® Ti Barbs Cervical Spacer System is an anterior cervical interbody fusion device indicated for use in skeletally mature patients with degenerative disc disease (DDD) with accompanying radicular symptoms at one level from C2-T1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six weeks of non-operative treatment. The Pro-Link® & Pro-Link® Ti Barbs Cervical Spacer System is to be used with autogenous bone graft and implanted via an anterior approach.

The Pro-Link® & Pro-Link® Ti Barbs Cervical Spacer System is an integrated cervical interbody fusion device intended to be used with two (2) titanium bone barbs. The Pro-Link® & Pro-Link® Ti Barbs Cervical Spacer System must be used with supplemental fixation (e.g., anterior plate, posterior cervical screw).

Technological Characteristics:
The Pro-Link® & Pro-Link® Ti Barbs 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 titanium alloy (Ti-6Al-4V ELI) as described by ASTM F136. This is the same material used in the predicate devices.

Substantial Equivalence:
The Pro-Link® & Pro-Link® Ti Barbs Cervical Spacer System was shown to be substantially equivalent to the predicate devices in indications for use, design, function, materials used and performance.

Conclusion:
The information presented demonstrates the substantial equivalency of the Pro-Link® & Pro-Link® Ti Barbs Cervical Spacer System.