April 30, 2021

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

Re: K210061
Trade/Device Name: ProLift® Lateral HELO Fixated
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVD, MAX
Dated: January 28, 2021
Received: February 1, 2021

Dear Ms. 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 (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/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 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 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,

Brent Showalter -S

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)*
K210061

Device Name
ProLift Lateral HELO Fixated

Indications for Use *(Describe)*
The The ProLift® Lateral HELO Fixated is an interbody fusion device intended for use in patients with degenerative disc disease (DDD) at one or two contiguous levels of the lumbosacral spine (L2-S1). DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) months of non-operative treatment. In addition, these patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). The ProLift® Lateral HELO Fixated is to be filled with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone. The ProLift® Lateral HELO Fixated must be used with FDA cleared supplemental fixation. The ProLift® Lateral HELO Fixated may optionally be used with two bone screws.

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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K210061
510(k) Summary
ProLift Lateral HELO Fixated

Submitted By: Life Spine, Inc.
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510(k) Contact: Angela Batker
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Fax: 847-884-6118

Date Prepared: April 5th, 2021

Trade Name: ProLift Lateral HELO Fixated

Common Name: Intervertebral Body Fusion Device

Classification: MAX, CFR 888.3080, Class II
OVD, CFR 888.3080, Class II

Primary Predicate: Life Spine ProLift Lateral Fixated (K200338)

Additional Predicate: Life Spine TruLift Expandable Cage (K201721)
Life Spine ProLift Expandable System (K173182)
Globus Elsa Spacer (K161379)
Life Spine Plateau Spacer System (K080411)

Device Description:
The ProLift® Lateral HELO Fixated 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 alloy (Ti-6Al-4V ELI) as described by ASTM F136. The implant allows packing of autograft bone graft and/or allogeneic bone graft composed of cancellous and/or corticocancellous bone to help promote fusion. The superior and inferior surfaces have teeth to assist in the interface with the vertebral bodies to prevent rotation and/or migration. The screws are manufactured in variable and fixed configurations with diameters of 5.5mm and 6.5mm and lengths of 25mm-60mm. The responsible surgeon will determine the correct size of the implant in accordance with the size of the individual patient.

All implants are provided and intended for SINGLE USE ONLY and should not be reused under any circumstances. Do not use any of the ProLift® Lateral HELO Fixated with components from any other System or manufacturer. The ProLift® Lateral HELO Fixated components should never be reused under any circumstances.

Indications for Use:
The ProLift® Lateral HELO Fixated is an interbody fusion device intended for use in patients with degenerative disc disease (DDD) at one or two contiguous levels of the lumbosacral spine (L2-S1). DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) months of non-operative treatment. In addition, these patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). The ProLift® Lateral HELO Fixated is to be filled with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone. The ProLift® Lateral HELO Fixated must be used with FDA cleared supplemental fixation. The ProLift® Lateral HELO Fixated may optionally be used with two bone screws.

Technological Characteristics:
The ProLift® Lateral HELO Fixated has the same technological charrateristics as the predicates devices including design, intended use, material composition, function and range of sizes.

Material:
This submission seeks clearance of a device made from titanium alloy (Ti-6Al-4V ELI) as described by ASTM F136. This this is the same material used in the predicate devices.

Performance Data:
Static axial compression, dynamic axial compression, static compressive shear and dynamic compressive shear testing according to ASTM F2077, was presented to demonstrated that the ProLift® Lateral HELO Fixated is safe, effective and substantially equivalent to the Pro-Lift Expandable System (K173182).

Substantial Equivalence:
The ProLift Lateral HELO Fixated 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 ProLift Lateral HELO Fixated.