DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Life Spine, Incorporated
Mr. Randy Lewis
General Manager
13951 South Quality Drive
Huntley, Illinois 60142

March 7, 2016

Re: K153400
Trade/Device Name: ProLift® Expandable System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: February 4, 2016
Received: February 5, 2016

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 Parts 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

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)*
K153400

Device Name
ProLift® Expandable System

Indications for Use *(Describe)*
The ProLift® Expandable 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. Patients with previous non-fusion spinal surgery at involved level(s) may be treated with the device. This device is intended to be used with autogenous bone graft and a supplemental internal spinal fixation system (e.g., pedicle screw or anterolateral plating system) that is cleared for use in the lumbosacral spine.

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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Food and Drug Administration
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510(k) Summary
ProLift® Expandable System

Submitted By: Life Spine, Inc.
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Fax: 847-884-6118

510(k) Contact: Randy Lewis
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Huntley, IL 60142
Telephone: 847-884-6117
Fax: 847-884-6118

Date Prepared: February 4th, 2015

Trade Name: ProLift® Expandable System

Common Name: Intervertebral Body Fusion Device

Classification: MAX, 21 CFR 888.3080, Class II

Primary Predicate : Opticage Interbody Fusion Device (K113527)

Additional Predicate: CoAlign Acculif Cages (K123752)
Synthes T-PAL Spacer (K100089)
Custom Spine Pathway AVID (K090566)
Kiscomedica L-Varlock (K080537)
EOI FLXfit IBF (K133813)
The Globus Caliber (K123231)

Device Description:

The ProLift® Expandable System is available in a range of sizes and footprints and can expand to the desired height (8mm to 16mm) 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 autogenous bone graft 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.

All implants are provided non-sterile and intended for SINGLE USE ONLY and should not be reused under any circumstances. **Do not use any of the ProLift Expandable System components with components from any other system or manufacturer. The ProLift Expandable System components should never be reused under any circumstances.**

Intended Use of the Device:

The ProLift® Expandable 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. Patients with previous non-fusion spinal surgery at involved level(s) may be treated with the device. This device is intended to be used with autogenous bone graft and a supplemental internal spinal fixation system (e.g., pedicle screw or anterolateral plating system) that is cleared for use in the lumbosacral spine.

Technological Characteristics:

The ProLift® Expandable System is substantially equivalent to the predicate systems in terms of design, materials, indications for use and sizing.

Performance Data:

Static compression, dynamic compression, static and dynamic shear testing according to ASTM F2077, as well as subsidence according to ASTM F2267, was presented to demonstrate the substantial equivalency of the Pro-Lift Spacer System.

Substantial Equivalence:

The ProLift® Expandable System was shown to be substantially equivalent to the predicate devices in indications for use, design, function, materials used and mechanical performance.