



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

April 17, 2020

Re: K200338  
Trade/Device Name: ProLift® Lateral Fixated  
Regulation Number: 21 CFR 888.3080  
Regulation Name: Intervertebral Body Fusion Device  
Regulatory Class: Class II  
Product Code: OVD, MAX  
Dated: February 7, 2020  
Received: February 11, 2020

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 (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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for  
Brent Showalter, Ph.D.  
Assistant Director (Acting)  
DHT6B: Division of Spinal Devices  
OHT6: Office of Orthopedic Devices  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)  
K200338

Device Name  
ProLift® Lateral Fixated

### Indications for Use (Describe)

The ProLift® Lateral 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 Fixated is to be filled with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone, may be used with two bone screws, and is to be used with supplemental fixation.

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**  
**ProLift® Lateral Fixated**

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

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

**Date Prepared:** April 13<sup>th</sup>, 2020

**Trade Name:** ProLift® Lateral Fixated

**Common Name:** Intervertebral Fusion Device With Integrated Fixation, Lumbar

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

**Primary Predicate:** Life Spine ProLift Expandable System (K191005)

**Additional Predicate:** Life Spine ProLift Expandable System (K173182)  
Globus Elsa (K161379)  
Life Spine Sentry (K180166)

**Device Description:**

The ProLift® Lateral 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.

**Intended Use of the Device:**

The ProLift® Lateral 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 Fixated System is to be filled with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone, may be used with two bone screws, and is to be used with supplemental fixation.

**Technological Characteristics:**

The ProLift® Lateral Fixated 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 this is the same material used in the predicate devices.

**Performance Data:**

Static compression, dynamic compression, static shear and dynamic shear testing according to ASTM F2077, was presented to demonstrate the substantial equivalency of the Pro-Lift Expandable System (K191005).

**Substantial Equivalence:**

The ProLift® Lateral 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 Fixated.