January 23, 2026

Life Spine, Inc.
Angela Batker
Director of RA/QA & Corporate Compliance Officer
13951 Quality Dr.
Huntley, Illinois 60142

Re: K253748
Trade/Device Name: Life Spine ProLift & ProLift Lateral and ProLift Lateral Fixated Expandable Spacer System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: October 22, 2025
Received: November 25, 2025

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K253748

Device Name
Life Spine ProLift & ProLift Lateral and ProLift Lateral Fixated Expandable Spacer System

Indications for Use *(Describe)*

ProLift

When used as an interbody fusion device, the ProLift® Expandable Spacer 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 autograft bone graft and/or allogeneic bone graft composed of cancellous and/or corticocancellous bone and a supplemental internal spinal fixation system (e.g., pedicle screw or anterolateral plating system) that is cleared for use in the lumbosacral spine.

ProLift Lateral Fixated

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.

510(k) Summary
ProLift, ProLift Lateral and ProLift Lateral Fixated Expandable Spacer System

Submitted By: Life Spine, Inc.
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510(k) Contact: Angela Batker
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Date Prepared: October 21st, 2025

Trade Name: Life Spine ProLift & ProLift Lateral and ProLift Lateral Fixated Expandable Spacer System

Common Name: Intervertebral Body Fusion Device

Classification: MAX, CFR 888.3080, Class II (ProLift and ProLift Lateral)
MAX/OVD, CFR 888.3080, Class II (ProLift Lateral Fixated)

Primary Predicate: Life Spine ProLift Expandable Spacer System (K250373)

Secondary Predicate: Life Spine ProLift Lateral Expandable Spacer System (K193258)
Life Spine ProLift Lateral Fixated Expandable System (K200338)

Device Description:

ProLift

The ProLift® Expandable Spacer System is available in a range of sizes and footprints and can expand to the desired height (8mm to 26mm) 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.

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

ProLift Lateral Fixated

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.

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 Fixated with components from any other system or manufacturer. The ProLift® Lateral Fixated components should never be reused under any circumstances.**

Intended Use of the Device:

ProLift

When used as an interbody fusion device, the ProLift® Expandable Spacer 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 autograft bone graft and/or allogeneic bone graft composed of cancellous and/or corticocancellous bone and a supplemental internal spinal fixation system (e.g., pedicle screw or anterolateral plating system) that is cleared for use in the lumbosacral spine.

ProLift Lateral Fixated

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.

Technological Characteristics:

The ProLift Expandable Spacer System is substantially equivalent to the predicate systems in terms of design, materials, and 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.

Performance Data:
Through the Comparison Analysis it is determined that the mechanical performance has not change as the worst case is still the same and therefore is substantially equivalent to the Life Spine ProLift Lateral Expandable Spacer System (K193258) and ProLift Lateral Fixated Expandable Spacer System (K200338). The ProLift Expandable Spacer System (K250373) has no design changes since last 510k just adding MRI Conditional to indications.

MRI Compatibility:
MRI Compatibility covers ProLift Micro, ProLift and ProLift Lateral the implants were tested to meet ASTM F2182, the testing passed with the product being MRI Conditional.

Substantial Equivalence:
The ProLift, ProLift Lateral and ProLift Lateral Fixation Expandable 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 ProLift, ProLift Lateral and ProLift Lateral Fixation Expandable Spacer System.