



December 5, 2022

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

Re: K221806

Trade/Device Name: TruLift® Lateral Expandable Spacer System & Lateral Plate System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX, KWQ
Dated: November 7, 2022
Received: December 8, 2022

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

Indications for Use

510(k) Number (if known)
K221806

Device Name
TruLift® Lateral Expandable Spacer System & Lateral Plate System

Indications for Use (Describe)

When used as an interbody fusion device, the TruLift® Lateral 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. The TruLift® Lateral Expandable Spacer can also be connected to the Lateral Plate System by a set screw.

The Lateral Plate System is intended to be used as a non-pedicle lateral or anterolateral fixation system in skeletally mature patients and is intended to provide immobilization and stabilization of spinal segments, as an adjunct to fusion in the treatment of the following acute and chronic instabilities of the thoracic and lumbar spine. It may be used from levels T1-L5 with the following indications:

- Degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies)
- Spondylolisthesis
- Spinal stenosis
- Spinal deformities (i.e., scoliosis, kyphosis, and/or lordosis)
- Tumor
- Pseudoarthrosis
- Failed previous fusion
- Trauma (i.e., fracture or dislocation)

The Lateral Plate System, 1-hole buttress configuration is intended for use in conjunction with traditional supplemental fixation to maintain the relative position of interbody spacers during spinal fusion. The 1-hole plate is not intended for use in load-bearing applications. The Lateral Plate System can also be connected to the TruLift® Lateral Spacer System by a set 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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K221806
510(k) Summary
Trulift® Lateral Expandable Spacer System & Lateral Plate System

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Date Prepared: November 2, 2022

Trade Name: Trulift® Lateral Expandable Spacer System & Lateral Plate System

Common Name: Intervertebral Body Fusion Device

Classification: MAX, CFR 888.3080, Class II
KWQ, CFR 888.3060, Class II

Primary Predicate: Life Spine ProLift Expandable System (K191005)

Additional Predicate: Life Spine TruLift Expandable System (K201721)
Life Spine ProLift HELO Expandable System (K210061)
Life Spine Plateau-X (K201500)
Sirion Lateral Lumbar Interbody Fusion (K202495)
Life Spine 2-Hole Lateral Plating System (K172131)

Device Description:

The TruLift® Lateral Expandable Spacer 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 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 TruLift® Lateral Expandable Spacer System components with components from any other system or manufacturer. The TruLift® Lateral Expandable Spacer System components should never be reused under any circumstances.**

The Lateral Plate System consists of a variety of plates and screws to suit the individual pathology and anatomical conditions of the patient. All components are fabricated and manufactured from titanium alloy 6AL-4V-ELI per ASTM F-136. The plates are manufactured in a variety of configurations with options including different lengths and curvature. The screws are manufactured in variable and fixed configurations with diameters and lengths. Fixation is provided by bone screws inserted through the plates and into the vertebral body of the Lumbar spine using an anterior approach. The responsible surgeon will determine the correct size of the implant in accordance with the size of the individual patient.

The Lateral Plate System also utilizes a variety of standard orthopedic instruments to assist in the placement of the devices.

Do not use any of the Lateral Plate System components with components from any other system or manufacturer. The Lateral Plate System components should never be reused under any circumstances.

Intended Use of the Device:

When used as an interbody fusion device, the TruLift® Lateral 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.

The TruLift® Lateral Expandable Spacer can also be connected to the Lateral Plate System by a set screw.

The Lateral Plate System is intended to be used as a non-pedicle lateral or anterolateral fixation system in skeletally mature patients and is intended to provide immobilization and stabilization of spinal segments, as an adjunct to fusion in the treatment of the following acute and chronic instabilities of the thoracic and lumbar spine. It may be used from levels T1-L5 with the following indications:

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The Lateral Plate System, 1-hole buttress configuration is intended for use in conjunction with traditional supplemental fixation to maintain the relative position of interbody spacers during

spinal fusion. The 1-hole plate is not intended for use in load-bearing applications. The Lateral Plate System can also be connected to the TruLift® Lateral Spacer System by a set screw.

Technological Characteristics:

The Trulift® Lateral Expandable Spacer System is substantially equivalent to (ProLift Lateral K191005) in terms of design, materials, indications for use and sizing. The Lateral Plate System is substantially equivalent to the predicate systems in terms of indications to the Sirion Lateral Lumbar Interbody Fusion (K202495), substantially equivalent in design and materials to Life Spine 2-hole Lateral Plating System (K172131).

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:

Plates

ASTM F1717 Dynamic Axial Compression Bending, Static Axial Compression Bending, Static Torsion

These test are equivalent Life Spine 2-Hole Lateral Plating System (K172131)

Interbody

ASTM F2077 Static Axial Compression, Static Compressive Shear, Dynamic Axial Compression and Dynamic Compressive Shear

ASTM F2267 Induced Subsidence of Intervertebral Body Fusion Device under Static Axial Compression

These tests are equivalent Life Spine ProLift Expandable System (K191005).

Substantial Equivalence:

The Trulift® Lateral Expandable Spacer System & Lateral Plate 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 the Trulift® Lateral Expandable Spacer System & Lateral Plate System.