November 16, 2022

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

Re: K222628
Trade/Device Name: Life Spine ALIF Buttress Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: August 22, 2022
Received: August 31, 2022

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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Anne D. Talley -S for

Colin O'Neill, M.B.E.
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)*
K222628

Device Name
Life Spine ALIF Buttress Plate System

Indications for Use *(Describe)*
The Life Spine ALIF Buttress Plate System in conjunction with traditional rigid fixation is intended for use in spinal fusion procedures of the thoracolumbar to S1 spinal region as a means to maintain the relative position of weak bony tissue such as allografts or autografts. This device is not intended for load bearing applications.

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
ALIF Buttress Plate

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

510(k) Contact: Angela Batker
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Telephone: 847-884-6117
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Date Prepared: August 24th, 2022

Trade Name: Life Spine ALIF Buttress Plate System

Common Name: Appliance, Fixation, Spinal Intervertebral Body

Classification: KWQ, 21 CFR 888.3060 Spinal Intervertebral Body Fixation Orthosis, Class II

Primary Predicate: Vail Buttress Plate System (K180755)

Additional Predicate: RCS Anterior Buttress Plate System (K092659)
Life Spine Sentry Lateral Plate System (K180166)

Device Description:
The Life Spine ALIF Buttress 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 Ti-6Al-4V-ELI per ASTM F-136.
All implants are intended for single use only and should not be reused under any circumstances. **Do not use any of the ALIF Buttress Plate System components with components from any other system or manufacturer. The ALIF Buttress Plate System components should never be reused under any circumstances**.

Indications for Use of the Device:
The Life Spine ALIF Buttress Plate System in conjunction with traditional rigid fixation is intended for use in spinal fusion procedures of the thoracolumbar to S1 spinal region as a means to maintain the relative position of weak bony tissue such as allografts or autografts. This device is not intended for load bearing applications.

Technological Characteristics:
The ALIF Buttress Plate System 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.

Substantial Equivalence:
The ALIF Buttress Plate System was shown to be substantially equivalent to the predicate devices in indications for use, design, function, materials used and performance.

Conclusion:
The information presented demonstrates the substantial equivalency of the ALIF Buttress Plate System.