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

September 18, 2020

Re: K201538
Trade/Device Name: Life Spine SIMPACT Sacroiliac Joint Fixation System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC, OUR
Dated: June 8, 2020
Received: June 9, 2020

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,

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)*
K201538

Device Name
Life Spine SIMPACT Sacroiliac Joint Fixation System

Indications for Use *(Describe)*
The Life Spine SIMPACT Sacroiliac Joint Fixation System is intended for sacroiliac fusion for the following conditions:
• Sacroiliac joint dysfunction that is a direct result of sacroiliac joint disruption and degenerative sacroiliitis. This includes conditions whose symptoms began during pregnancy or in the peripartum period and have persisted postpartum for more than 6 months.
• To augment immobilization and stabilization of the sacroiliac joint in skeletally mature patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion.
• Acute, non-acute, and non-traumatic fractures involving the sacroiliac joint.

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
Life Spine SIMPACT Sacroiliac Joint Fixation System

Submitted By: Life Spine, Inc.
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Huntley, IL 60142
Telephone: 847-884-6117
Fax: 847-884-6118

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

Date Prepared: June 8th, 2020

Trade Name: Life Spine SIMPACT Sacroiliac Joint Fixation System

Common Name: Spinal Interlaminal Fixation Orthosis

Classification: HWC, CFR 888.3040, Class II
OUR, CFR 888.3040, Class II

Primary Predicate: Life Spine Sacroiliac Joint Fixation Screw System (K141246)

Additional Predicates: Life Spine Sacroiliac Joint Fixation Screw System (K180749)
Zyga Tech. Simmetry Sacroiliac Joint Fixation Screw System (K141549)
Si-Bone iFuse Implant System (K193524)

Device Description:

The Life Spine SIMPACT Sacroiliac Joint Fixation System consists of fully threaded screws and partially threaded cannulated screws in various diameters and lengths to enhance sacroiliac joint fusion. All components are fabricated and manufactured from titanium alloy 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 Life Spine Simpact Sacroiliac Joint Fixation System components with components from any other system or manufacturer. The Life Spine Simpact Sacroiliac Joint Fixation System components should never be reused under any circumstances.

Indications for Use:

The Life Spine SIMPACT Sacroiliac Joint Fixation System is intended for sacroiliac fusion for the following conditions:

• Sacroiliac joint dysfunction that is a direct result of sacroiliac joint disruption and degenerative sacroiliitis. This includes conditions whose symptoms began during pregnancy or in the peripartum period and have persisted postpartum for more than 6 months.

• To augment immobilization and stabilization of the sacroiliac joint in skeletally mature patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion.

• Acute, non-acute, and non-traumatic fractures involving the sacroiliac joint.

Technological Characteristics:

The Life Spine Simpact Sacroiliac Joint Fixation 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 implant grade (Ti-6AL-4V) Titanium alloy according to F136. This this is the same material used in the predicate devices.

Performance Data:

Testing according to Static Screw Pull-Out & Screw Driving Torque testing to ASTM F543 (A1,A2 & A3) was presented to demonstrate the substantial equivalency of the Life Spine Slotted Fixation System (K141246).

Substantial Equivalence:

The Life Spine Simpact Sacroiliac Joint Fixation 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 Life Spine Simpact Sacroiliac Joint Fixation System.