June 15, 2018

Life Spine Inc.
Mr. Randy Lewis
General Manager
13951 South Quality Drive
Huntley, Illinois 60142

Re: K180749
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: OUR, HWC
Dated: March 12, 2018
Received: March 22, 2018

Dear Mr. Lewis:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ronald P. Jean -S

for Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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)*
K180749

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 joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis.

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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Fax: 847-884-6118

510(k) Contact: Randy Lewis
Life Spine, Inc.
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Telephone: 847-884-6117
Fax: 847-884-6118

Date Prepared: June 12th, 2018

Trade Name: Life Spine SIMPACT Sacroiliac Joint Fixation System

Common Name: Spinal Sacroiliac Device

Purpose: Life Spine SIMPACT Sacroiliac Joint Fixation System

Classification: OUR, CFR 888.3040 Smooth or threaded metallic bone fixation fastener, Class II
HWC, CFR 888.3040 Smooth or threaded metallic bone fixation fastener, Class II

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

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. The purpose of this submission is to add the Tri-Fin Screw to the SIMPACT Sacroiliac Joint Fixation System. 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 joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis.

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:

Engineering analyses and Static Screw Pull-Out & Screw Driving Torque testing to ASTM F543 (A2 & A3) were presented to demonstrate the substantial equivalency of the Life Spine Sacroiliac Joint 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.