



December 15, 2021

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

Re: K212903

Trade/Device Name: 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: October 14, 2021  
Received: October 15, 2021

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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

## Indications for Use

510(k) Number (if known)

K212903

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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Telephone: 847-884-6117  
Fax: 847-884-6118

**510(k) Contact:** Angela Batker  
Life Spine, Inc.  
13951 S. Quality Drive  
Huntley, IL 60142  
Telephone: 847-884-6117  
Fax: 847-884-6118

**Date Prepared:** September 10th, 2021

**Trade Name:** Life Spine SIMPACT Sacroiliac Joint Fixation System

**Common Name:** Spinal Interlaminar Fixation Orthosis

**Classification:** OUR, 21 CFR 888.3040, Class II  
HWC, 21 CFR 888.3040, Class II

Smooth or Threaded Metallic Bone Fastener

**Primary Predicate:** Medtronic, Inc. Rialto Sacroiliac Fusion System (K161210)

**Additional Predicates:** Life Spine Sacroiliac Joint Fixation Screw System (K201538,K180749,K141246)  
Medtronic, Inc. MSB Sacroiliac Joint Fusion Device (K110472)

**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. The purpose of this submission is to add the Posterior Oblique approach technique.

**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 of the Device:**

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 Simpect 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:**

There are no new devices in this submission, only Design of Experiment validating Posterior Oblique approach.

**Substantial Equivalence:**

The Life Spine Simpect 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 Simpect Sacroiliac Joint Fixation System.