July 29, 2024

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

Re: K241464
Trade/Device Name: ARx® SAI Implant System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: OUR, NKB
Dated: May 16, 2024
Received: May 23, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

STEPHANIE SMITH -S

for Ronald P. Jean, Ph.D.
Director (Acting)
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)*

K241464

Device Name
ARx® SAI Implant System

Indications for Use *(Describe)*

The ARx® SAI Implant System is intended for sacroiliac joint fusion for the following conditions:
• Sacroiliac joint dysfunction and degenerative sacroiliitis include 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.

When connected to Arx® Spinal System, the ARx SAI Implant System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to thoracolumbosacral fusion for the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine:
• Degenerative disc disease (DDD) as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies.
• Spondylolisthesis
• Trauma (i.e., fracture or dislocation)
• Spinal Stenosis
• Deformities or curvatures (i.e., scoliosis, kyphosis and/or lordosis)
• Spinal tumor
• Pseudarthrosis
• Failed previous fusion

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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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**510(k) Summary**
**ARx® SAI Implant System**

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

**Date Prepared:** May 20th, 2024

**Trade Name:** ARx® SAI Implant System

**Common Name:** Smooth or Threaded Metallic Bone Fixation Fastener

**Classification:** OUR CFR 888.3040 Smooth or Threaded Metallic Bone Fixation Fastener, Class II
NKB CFR 888.3070, Thoracolumbosacral Pedicle screw system, Class II

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

**Additional Predicates:** Life Spine ARx Spinal Screw System K203163
SI-Bone, Inc. iFuse Bedrock Granite Implant System K233508
Life Spine SIMPACT Sacroiliac Joint Fixation System K180749 & K201538

**Device Description:**
The ARx® SAI Implant System consists of an assortment of implants in various lengths and diameters, and associated instruments sets for both Open and minimally invasive [MIS] approaches. The bone screw, head, and taper lock are assembled during manufacturing to create the ARx® SAI Implant System screw assembly component. It is intended to provide sacroiliac joint fusion in the sacral alar iliac (SAI) trajectory, and foundational stabilization when connected to pedicle screw fixation systems in both the SAI and the Iliac trajectories. Additionally, ARx® SAI Implant System can be placed into the S1 pedicle. It is designed for connection to the Arx Pedicle Screw System 5.5mm or 6.0mm diameter titanium alloy or cobalt chrome alloy spinal fixation rods. The ARx® SAI Implant System implant components are made from Titanium alloy (Ti- 6Al-4V ELI) as described by ASTM Fl36.

**Indications for Use of the Device**:
The ARx® SAI Implant System is intended for sacroiliac joint fusion for the following conditions:

• Sacroiliac joint dysfunction and degenerative sacroiliitis include 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.

When connected to Arx® Spinal Screw System, the ARx SAI Implant System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to thoracolumbosacral fusion for the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine:
• Degenerative disc disease (DDD) as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies.
• Spondylolisthesis
• Trauma (i.e., fracture or dislocation)
• Spinal Stenosis
• Deformities or curvatures (i.e., scoliosis, kyphosis and/or lordosis)
• Spinal tumor
• Pseudarthrosis
• Failed previous fusion

**Material:**
This submission seeks clearance of a device made from titanium alloy (Ti-6Al-4V ELI) as described by ASTM F136. This is the same material used in the predicate devices.

**Performance Data:**
An engineering analysis to compare technological features and finite element analysis for cantilever bending and torque to failure were performed between the ARx® SAI Implant System and primary predicate device. Screw pullout and driving torque testing per ASTM F543 were performed. All performance data demonstrates substantial equivalence to the predicate devices.

**Substantial Equivalence:**
The ARx® SAI Implant 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 ARx® SAI Implant System.