April 16. 2026

Life Spine, Inc.
Angela Batker
Director of RA/QA & Corporate Compliance Officer
13951 Quality Dr.
Huntley, Illinois 60142

Re: K254274
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: March 25, 2026
Received: March 25, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

COLIN O'NEILL -S

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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K254274

Please provide the device trade name(s).

ARx® SAI Implant System

Please provide your Indications for Use below.

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 compatible pedicle screws with 5.5- or 6.0-mm posterior rods made from either titanium alloys or cobalt chrome, 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

Please refer to the Instructions for Use/Package Insert for additional information on compatible systems.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary
ARx® SAI Implant System

Submitted By: Life Spine, Inc.
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510(k) Contact: Angela Batker
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Date Prepared: April 16th , 2026

Trade Name: ARx® SAI Implant System

Common Name: Thoracolumbosacral Pedicle Screw System

Classification: OUR CFR 888.3040, Class II
NKB, CFR 888.3070, Class II

Primary Predicate: Life Spine ARx SAI Implant System (K241464)

Additional Predicate: Life Spine Sacroiliac Joint Fixation Screw System (K141246)
Life Spine ARx SAI Implant System (K241464)
SI-Bone, Inc. iFuse Bedrock Granite Implant System (K233508)

Device Reference: Life Spine Arx MIS Spinal Screw System (K233455)

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 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 (when used with commercially available sacroiliac joint fusion promoting devices), 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 any compatible 5.5mm or 6.0mm diameter titanium alloy or cobalt chrome alloy spinal fixation rods. Please refer to the additional information section in the Instructions for Use/Package Insert on compatible pedicle screw system rods.

Indications for Use:
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 compatible pedicle screws with 5.5- or 6.0-mm posterior rods made from either titanium alloys or cobalt chrome, 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.
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- Spinal tumor
- Pseudarthrosis
- Failed previous fusion

Please refer to the Instructions for Use/Package Insert for additional information on compatible systems.

Performance Data:
The ARx® SAI Implant System was dimensionally compared to the predicate. Additionally, the connection of the ARx® SAI Implant System to commercially available representative rods was evaluated with the following mechanical testing:

- Static axial grip per ASTM F1798
- Static torsional grip per ASTM F1798
- Dynamic compression bending per ASTM F1717

Testing was performed on a range of rod diameters and manufacturing methods to demonstrate compatibility with the ARx® SAI Implant System.

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 ARx® SAI Implant System. The information presented demonstrates that the ARx® SAI Implant System is substantially equivalent to the predicate devices.