March 31, 2022

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

Re: K220025
Trade/Device Name: ARx® Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB, KWP
Dated: December 13, 2021
Received: January 5, 2022

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) 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

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)*
K220025

Device Name
ARx® Spinal System

Indications for Use *(Describe)*
The ARx® Spinal System implants are non-cervical spinal fixation devices intended for posterior spine (T1 to S2/ilium) and posterior hook fixation (T1-L5) in skeletally mature patients and for pediatric patients to treat adolescent idiopathic scoliosis. It provides stabilization and immobilization of spinal segments as an adjunct to fusion in the treatment of acute and chronic instabilities or deformities of the posterior thoracic, lumbar, and sacral spine. These devices are to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

When used as a posterior spine thoracic/lumbar system, the ARx® Spinal System is indicated for one or more of the following: (1) degenerative disc disease (is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), (2) trauma (i.e. fracture or dislocation), (3) curvatures and spinal deformity (scoliosis, kyphosis, and/or lordosis), (4) spinal tumor, (5) failed previous fusion (pseudarthrosis), (6) spinal stenosis, (7) spondylolisthesis.

In order to achieve additional levels of fixation in skeletally mature patients, the ARx® Spinal System 5.5/6.0 rod system may be connected to the Solstice OccipitoCervicoThoracic Fixation System's 3.5mm rod.

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.

510(k) Summary
ARx® Spinal System

Submitted By: Life Spine, Inc.
13951 S. Quality Drive
Huntley, IL 60142
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: December 28th, 2021

Trade Name: ARx® Spinal System

Common Name: Thoracolumbosacral Pedicle Screw System

Classification: NKB and KWP; CFR 888.3070 and CFR 888.3050; Class II

Primary Predicate: Life Spine Nautilus Transition System K141222

Additional Predicate: Life Spine Conquest K090320
Zimmer Biomet Vitality+ Spinal Fixation System K171907
Life Spine ARx® Spinal System (K200070, K203163, K191575, K210549)
ChoiceSpine Blackbird Cervical-Thoracic Spinal Fixation System K133214 OrthoFix Connector System K190751
Life Spine Solstice OCT System (K170804 & K143249)

Device Description:
The ARX® Spinal System consists of screws and longitudinal rods intended to provide temporary stabilization and immobilization following surgery to fuse a portion of the thoracic, lumbar, and/or sacral spine. The ARX® Spinal System consists of an assortment of connectors, cross connectors, rods, hooks and screws. The bone screw, head, and taper lock are assembled together during manufacturing to create the ARX® Spinal System screw assembly component. The ARX® Spinal System implant components are made from titanium alloy (Ti- 6Al-4V ELI) as described by ASTM F136 and Cobalt Chrome (Co-28Cr-6Mo) as described by ASTM F1537. Do not use any of the ARX® Spinal System components with the components from any other system or manufacturer.

Indications for Use:
The ARx® Spinal System implants are non-cervical spinal fixation devices intended for posterior spine (T1 to S2/ilium) and posterior hook fixation (T1-L5) in skeletally mature patients and for pediatric patients to treat adolescent idiopathic scoliosis. It provides stabilization and immobilization of spinal segments as an adjunct to fusion in the treatment of acute and chronic instabilities or deformities of the posterior thoracic, lumbar, and sacral spine. These devices are to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

When used as a posterior spine thoracic/lumbar system, the ARx® Spinal System is indicated for one or more of the following: (1) degenerative disc disease (is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), (2) trauma (i.e. fracture or dislocation), (3) curvatures and spinal deformity (scoliosis, kyphosis, and/or lordosis), (4) spinal tumor, (5) failed previous fusion (pseudarthrosis), (6) spinal stenosis, (7) spondylolisthesis.

In order to achieve additional levels of fixation in skeletally mature patients, the ARx® Spinal System 5.5/6.0 rod system may be connected to the Solstice OccipitoCervicoThoracic Fixation System's 3.5mm rod.

Material:
This submission seeks clearance of a device made from titanium alloy (Ti-6Al-4V ELI) as described by ASTM F136. There are devices included in this submission that have already been 510k approved that use cobalt chrome (Co-28Cr-6Mo) per ASTM 1537. This is the same material used in the predicate devices.

Performance Data:
The ARx® Spinal System was tested according to ASTM F1717 & F1798 includes: Static Axial Compression Bending Testing, Static Torsion, Dynamic Compression Testing, Axial Grip, & Torsional Grip Testing was presented to demonstrate the substantial equivalency of the Life Spine Nautilus K123373.

Substantial Equivalence:
The ARx® Spinal 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® Spinal System.