March 13, 2019

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

Re: K183430
Trade/Device Name: Modular Spinal Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: NKB
Dated: March 5, 2019
Received: March 6, 2019

Dear Ms. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 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)*
K183430

Device Name
Modular Spinal Fixation System

Indications for Use *(Describe)*

Internal fixation implants are load-sharing devices intended to stabilize and maintain alignment until normal healing occurs. Implants are not intended to replace normal body structures or bear the weight of the body in the presence of incomplete bone healing.

The Modular Spinal Fixation System, when properly used, is intended for posterior pedicle screw fixation of the non-cervical posterior spine in skeletally mature patients and for pediatric patients to treat adolescent idiopathic scoliosis (4.75 systems only). It provides stabilization and immobilization of spinal segments as an adjunct to fusion. Pediatric pedicle screw fixation is limited to a posterior approach.

When used as a posterior spine thoracic/lumbar system, the Modular Spinal Fixation 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 (scoliosis, kyphosis, and/or lordosis), (4) spinal tumor, (5) failed previous fusion (6) pseudarthrosis, (7) spinal stenosis, (8) spondylolisthesis.

In order to achieve additional levels of fixation in skeletally mature patients, the Modular Spinal Fixation System may be connected to the Solstice OccipitoCervicoThoracic Fixation System's 3.5mm rod. The Modular Spinal Fixation System is intended to be used with autograft or allograft.

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
Modular Spinal Fixation System

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510(k) Contact: Angela Batker
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Date Prepared: March 13th, 2019

Trade Name: Modular Spinal Fixation System

Common Name: Pedicle Screw Spinal System

Classification: NKB, CFR 888.3070, Class II

Primary Predicate: Orthofix Janus Spinal System (K171082)

Additional Predicate: Life Spine Centerline Spinal System (K151196)
Life Spine Nautilus Spinal System (K140457)

Device Description:
The Modular Spinal Fixation System consists of an assortment of rods, modular screws, modular tulips, cross connectors and offset connectors. The head and taper lock are assembled together during manufacturing to create the modular tulip assembly. The cross connectors are also assembled during manufacturing. The Modular Spinal Fixation System implant components are made from titanium alloy (Ti-6Al-4V ELI) as described by ASTM F136 and cobalt chrome (Co-28Cr-6Mo) per ASTM 1537.

All implants are intended for single use only and should not be reused under any circumstances. Do not use any of the Life Spine Modular Spinal Fixation System components with components from any other system or manufacturer.

Intended Use of the Device:
Internal fixation implants are load-sharing devices intended to stabilize and maintain alignment until normal healing occurs. Implants are not intended to replace normal body structures or bear the weight of the body in the presence of incomplete bone healing.

The Modular Spinal Fixation System, when properly used, is intended for posterior pedicle screw fixation of the non-cervical posterior spine in skeletally mature patients and for pediatric patients to treat adolescent idiopathic scoliosis (4.75 systems only). It provides stabilization and immobilization of spinal segments as an adjunct to fusion. Pediatric pedicle screw fixation is limited to a posterior approach.

When used as a posterior spine thoracic/lumbar system, the Modular Spinal Fixation 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 (scoliosis, kyphosis, and/or lordosis), (4) spinal tumor, (5) failed previous fusion (6) pseudarthrosis, (7) spinal stenosis, (8) spondylolisthesis.

In order to achieve additional levels of fixation in skeletally mature patients, the Modular Spinal Fixation System may be connected to the Solstice® OccipitoCervicoThoracic Fixation System's 3.5mm rod. The Modular Spinal Fixation System is intended to be used with autograft or allograft.

Technological Characteristics:
The Modular Spinal 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 titanium alloy (Ti-6Al-4V ELI) as described by ASTM F136 and cobalt chrome (Co-28Cr-6Mo) per ASTM 1537. This this is the same material used in the predicate devices.

Performance Data:
Testing according to ASTM F543 & F1717 included Static Axial Compression Bending, Static Torsion, Dynamic Axial Compression Bending and Dissociation tests was presented to demonstrate the substantial equivalency of the Life Spine Nautilus K140457.

Substantial Equivalence:
The Modular Spinal 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 Modular Spinal Fixation System.