



December 11, 2018

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

Re: K181625

Trade/Device Name: Life Spine Resolute™ Threaded Cage System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: November 11, 2018
Received: November 14, 2018

Dear Ms. Batke:

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,


Melissa Hall -S

For Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K181625

Device Name

Life Spine Resolute™ Threaded Cage System

Indications for Use (Describe)

The RESOLUTE Threaded Cage System is intended to be used bilaterally for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels (L2-S1). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. DDD patients may also have up to Grade 1 spondylolisthesis at the involved level(s). It is to be used in patients who have had at least six months of non-operative treatment.

The Resolute Threaded Cage System intended to be used with autograft bone graft and/or allogeneic bone graft composed of cancellous and/or corticocancellous bone and a supplemental internal spinal fixation system (e.g., pedicle screw or anterolateral plating system) that is cleared for use in the lumbosacral spine.

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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K181625
510(k) Summary
Life Spine Resolute™ Threaded Cage 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: June 15th, 2018

Trade Name: Life Spine Resolute™ Threaded Cage System

Common Name: Intervertebral Body Fusion Device

Classification: MAX, CFR 888.3080 Class II

Primary Predicate: Asfora Bullet Cage K112648/K090048

Secondary Predicate: Life Spine, Inc Plateau Ti K130630
Life Spine, Inc Plateau K080411/K111569

Device Description:

The Resolute Threaded Cage System implants are devices intended to serve as an intervertebral body fusion device. The implant is available in a range of diameters and lengths to suit the individual pathology and anatomical conditions of the patient. It is fabricated and manufactured from titanium alloy (Ti-6Al-4V ELI) described by ASTM F136. The implant is hollow to permit packing with autograft bone graft and/or allogeneic composed of cancellous and/or corticocancellous bone and a supplemental fixation system (e.g., pedicle screw or anterolateral plating system) that is cleared for use in the lumbosacral spine to help promote intervertebral body fusion. The cylindrical surface has threads to assist in the interface with the vertebral endplates to prevent migration.

All implants are intended for single use only and should not be reused under any circumstances. **Do not use any of the Resolute Threaded Cage System components with components from any other system or manufacturer. The Resolute Threaded Cage System components should never be reused under any circumstances**

Indications for Use:

The RESOLUTE Threaded Cage System is intended to be used bilaterally for spinal fusion procedures in patients with degenerative disc disease (DDD) at one or two contiguous levels (L2-S1). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. DDD patients may also have up to Grade 1 spondylolisthesis at the involved level(s). It is to be used in patients who have had at least six months of non-operative treatment.

The Resolute Threaded Cage System intended to be used with autograft bone graft and/or allogeneic bone graft composed of cancellous and/or corticocancellous bone and a supplemental internal spinal fixation system (e.g., pedicle screw or anterolateral plating system) that is cleared for use in the lumbosacral spine.

Technological Characteristics:

The Life Spine Resolute Threaded Cage 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 is the same material used in the predicate devices.

Performance Data:

Testing according to ASTM F2077 included Static Axial Compression, Static Axial Compression Shear, Dynamic Compression Shear & Dynamic Axial Compression testing was presented to demonstrate the substantial equivalency of the Asfora Bullet Cage K112648/K090048.

Substantial Equivalence:

The Life Spine Resolute Threaded Cage 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 Resolute Threaded Cage System.