DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Life Spine, Inc.
Mr. Randy Lewis
General Manager
13951 South Quality Drive
Huntley, Illinois 60142

August 28, 2017

Re: K172131
Trade/Device Name: 2 Hole Lateral Plating System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: July 13, 2017
Received: July 14, 2017

Dear Mr. Lewis:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Mark N. Melkerson -S

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)*
K172131

Device Name
2 Hole Lateral Plating System

Indications for Use *(Describe)*
The 2 Hole Lateral Plating System is intended to be used as a non-pedicle lateral or anterolateral fixation system in skeletally mature patients and is intended to provide immobilization and stabilization of spinal segments, as an adjunct to fusion in the treatment of the following acute and chronic instabilities of the thoracic and lumbar spine. It may be used from levels T1-L5 with the following indications:
- Degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies)
- Spondylolisthesis
-Spinal stenosis
-Spinal deformities (i.e., scoliosis, kyphosis, and/or lordosis)
-Tumor
-Pseudoarthrosis
-Failed previous fusion
-Trauma (i.e., fracture or dislocation)

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
2 Hole Lateral Plating System

Submitted By: Life Spine, Inc.
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Fax: 847-884-6118

510(k) Contact: Randy Lewis
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13951 S. Quality Drive
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Telephone: 847-884-6117
Fax: 847-884-6118

Date Prepared: July 13th, 2017

Trade Name: 2 Hole Lateral Plating System

Common Name: Spinal intervertebral body fixation orthosis

Classification: KWQ, 21 CFR 888.3060, Class II

Primary Predicate : Orthofix Skyhawk (K140260)

Additional Predicate: Eminent Spine Black Diamond (K133194)
Globus Plymouth (K120092)
Nuvasive Lateral Plate (K091071)
Presidio Anterior Lumbar Plate (K132589)

Device Description:

The 2 Hole Lateral Plating System consists of a variety of plates and screws to suit the individual pathology and anatomical conditions of the patient. All components are fabricated and manufactured from titanium alloy 6AL-4V-ELI per ASTM F-136.

The plates are manufactured in a variety of configurations with options including lengths of 16mm-26mm. The screws are manufactured in variable and fixed configurations with diameters of 5.5mm and 6.5mm and lengths of 25mm-60mm. The responsible surgeon will determine the correct size of the implant in accordance with the size of the individual patient.

The 2 Hole Lateral Plating System also utilizes a variety of standard orthopedic instruments to assist in the placement of the devices.

Intended Use of the Device:

The 2 Hole Lateral Plating System is intended to be used as a non-pedicle lateral or anterolateral fixation system in skeletally mature patients and is intended to provide immobilization and stabilization of spinal segments, as an adjunct to fusion in the treatment of the following acute and chronic instabilities of the thoracic and lumbar spine. It may be used from levels T1-L5 with the following indications:
- Degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies)
- Spondylolisthesis
-Spinal stenosis
-Spinal deformities (i.e., scoliosis, kyphosis, and/or lordosis)
-Tumor
-Pseudoarthrosis
-Failed previous fusion
-Trauma (i.e., fracture or dislocation)

Technological Characteristics:
The 2 Hole Lateral Plating System is substantially equivalent to the predicate systems in terms of design, materials, indications for use and sizing.

Performance Data:
Static compression, dynamic compression and static torsion testing according ASTM F1717, as well as benchtop screw push out testing, was presented to demonstrate the substantial equivalency of The 2 Hole Lateral Plating System.

Conclusions:
The 2 Hole Lateral Plating System was shown to be substantially equivalent to the predicate devices in indications for use, design, function, materials used and mechanical performance.