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510(k) Summary
Life Spine Interspinous Fixation System

NOV - 5 2010

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Date Prepared: February 8, 2010

Trade Name: **Life Spine Interspinous Fixation System**

Common Name: Interspinous Process Fixation System

Classification: MNH, 888.3070, Class II, Spondylolisthesis Spinal Fixation Device System
MNI, 888.3070, Class II, Pedicle Screw Spinal System
KWP, 888.3050, Class II, Spinal Interlaminal Fixation Orthosis

Device Description:

The Life Spine Interspinous Fixation System is a posterior, non-pedicle supplemental fixation device, intended for use in the non-cervical spine (T1-S1). Implants are manufactured from titanium alloy per ASTM F136 and are available in a range of sizes to suit the individual pathology and anatomical conditions of the patient.

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 ARX® Spinal System, PILOT® Spinal System, PILOT® Posterior Lumbar Plating System, and CONQUEST® Spinal System, when properly used, are intended for posterior pedicle screw fixation of the non-cervical posterior spine in skeletally mature patients. They provide stabilization and immobilization of spinal segments as an adjunct to fusion.

When used as posterior spine thoracic/lumbar systems, the ARX Spinal System, PILOT Spinal System, PILOT Posterior Lumbar Plating System, and CONQUEST Spinal System are 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) pseudoarthrosis, (7) spinal stenosis, (8) spondylolisthesis.

The Life Spine Interspinous Fixation System is a posterior, non-pedicle supplemental fixation device, intended for use in the non-cervical spine (T1-S1). It is intended for plate fixation/attachment to the spinous processes for the purpose of achieving, in conjunction with autogenous bone graft, single level supplemental fusion in the following conditions: (1) degenerative disc disease (is defined as back pain of discogenic origin with degeneration of the disc as confirmed by patient history and radiographic studies), (2) trauma (i.e., fracture or dislocation), (3) spinal tumor, (4) spondylolisthesis. The Life Spine Interspinous Fixation System is not intended for stand-alone use.

Test Data:

The Life Spine Interspinous Fixation System was tested according to a modified version of ASTM Standard F1717-04. The tests performed were Static Axial Compression, Static Torsion, Static Axial Pullout, Dynamic Axial Compression, and Static Axial Grip Strength.

Testing Conclusions:

Analysis and interpretation of the test results show that the Life Spine device is equivalent, and in many cases superior, to the predicate devices.

Substantial Equivalence:

The Life Spine Interspinous Fixation System is substantially equivalent in design, materials, function and indications for use to the predicate devices presented.

Table 1: Comparison Analysis

Feature	Life Spine Interspinous Fixation System	Lanx Spinal Fixation System (K071877& K90252)	CD Horizon Spinous Process Plate (K032037)
Indications for Use	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 ARX Spinal System, PILOT Spinal System, PILOT Posterior Lumbar Plating System, and CONQUEST Spinal System, when properly used, are intended for posterior pedicle screw fixation of the non-cervical posterior spine in skeletally mature patients. They provide stabilization and immobilization of spinal segments as an adjunct to fusion. When used as posterior spine thoracic/lumbar systems, the ARX Spinal System, PILOT Spinal System, PILOT Posterior Lumbar Plating System, and CONQUEST Spinal System are 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) pseudoarthrosis, (7) spinal stenosis, (8) spondylolisthesis. The Life Spine Interspinous Fixation System is a posterior, non-pedicle supplemental fixation device, intended for use in the non-cervical spine (T1-S1). It is intended for plate fixation/attachment to the spinous process for the purpose of achieving	The Lanx Spinal Fixation System (SFS) is intended to be used to help provide immobilization and stabilization of the spinal segments as an adjunct to fusion of the thoracic, lumbar and/or sacral spine. The Lanx SFS is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion for treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine: severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra; degenerative spondylolisthesis with objective evidence of neurologic impairment; fracture; dislocation; scoliosis; kyphosis; spinal tumor; and failed previous fusion (pseudoarthrosis). The Lanx Spinous Process Fusion Plate (SPFP) is a posterior, non-pedicle supplemental fixation device, intended for use in the non-cervical spine (T1-S1). It is intended for plate fixation/ attachment to the spinous process for the purpose of achieving supplemental fusion in the following conditions: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); and/or spinal tumor. The Lanx SPFP is intended for use with bone graft material and is not intended for stand-alone use.	The CD HORIZON SPINOUS PROCESS Plate is posterior, non-pedicle supplemental fixation device, intended for use in the non-cervical spine (T1-S1). It is intended or plate fixation/attachment to spinous process for the purpose of achieving supplemental fusion in the following conditions: Degenerative disc disease – defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. Spodylolisthesis, Trauma (i.e., fracture or dislocation), Tumor. The CD HORIZON SPINOUS PROCESS Plate is not intended for stand-alone use.

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Table 1: Comparison Analysis

	supplemental fusion in the following conditions: (1) degenerative disc disease (is defined as back pain of discogenic origin with degeneration of the disc as confirmed by patient history and radiographic studies), (2) trauma (i.e., fracture or dislocation), (3) spinal tumor, (4) spondylolisthesis. The Life Spine Interspinous Fixation System is not intended for stand-alone use.		
Sizes	Overall Width: 14mm Lengths: 8mm-18mm; 2mm increments	Overall Widths: 8mm, 14mm Lengths: 8mm-18mm; 2mm increments	Overall length: 35mm, 45mm Height: 12mm Thickness (per plate): 3mm
Design / Description	The Life Spine Interspinous Fixation System is a posterior, non-pedicle supplemental fixation device, intended for use in the non-cervical spine (T1-S1). Implants are manufactured from or titanium alloy (6AL-4V-ELI per ASTM F136) and are available in a range of sizes to suit the individual pathology and anatomical conditions of the patient. The implants are designed to sit between two spinous processes in order to maintain distraction between the vertebrae. There are plates on both sides of the spinous processes, and the plates are translationally adjustable to one another to accommodate different widths. The plates include spikes which anchor the implant to the spinous processes to prevent migration.	The Lanx Spinous Process Fusion Plates are manufactured from titanium alloy per ASTM F136 and are available in a range of sizes to suit the individual pathology and anatomical conditions of the patient. The implants are designed to sit between two spinous processes in order to maintain distraction between the vertebrae. There are plates on both sides of the spinous processes, and the plates are translationally adjustable to one another to accommodate different widths. The plates include spikes which anchor the implant to the spinous processes to prevent migration.	The CD HORIZON SPINOUS PROCESS Plate is posterior, non-pedicle supplemental fixation device, intended for use in the non-cervical spine (T1-S1). It is intended or plate fixation/attachment to spinous process for the purpose of achieving supplemental fusion in the following conditions: Degenerative disc disease – defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. Spodylolisthesis, Trauma (i.e., fracture or dislocation), Tumor. The CD HORIZON SPINOUS PROCESS Plate is not intended for stand-alone use.
Material	Titanium alloy 6AL-4V-ELI per ASTM F136	Titanium alloy per ASTM F136	Titanium alloy per ASTM F136
Sterile / Non-Sterile	Supplied Non-Sterile	Supplied Non-Sterile	Supplied Non-Sterile

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Life Spine, Inc.
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NOV - 5 2010

Re: K100407
Trade/Device Name: Life Spine Interspinous Fixation System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: Class II
Product Code: KWP, MNI, MNH
Dated: October 21, 2010
Received: October 22, 2010

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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 yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Form

Indications for Use

510(k) Number (if known): K100407

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Device Name: **Life Spine Interspinous Fixation System**

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Prescription Use √ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100407