



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

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

November 20, 2015

Re: K152282
Trade/Device Name: Cam Lock Plating System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: October 30, 2015
Received: November 2, 2015

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

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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 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 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 -S

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)
K152282

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Device Name
Cam Lock Plating System

Indications for Use (Describe)

This system is intended for anterior interbody screw fixation of the cervical spine. The system is indicated for use in the temporary stabilization of the anterior spine from C2 to T1 during the development of cervical spinal fusions in patients with: 1.) Degenerative disc disease, DDD (as defined by neck pain of discogenic origin with degeneration of disc confirmed by patient history and radiographic studies); 2.) Spondylolisthesis; 3.) Trauma (including fractures or dislocations); 4.) Spinal cord stenosis; 5.) Deformity or curvatures (i.e. kyphosis, lordosis or scoliosis); 6.) Tumors; 7.) Pseudarthrosis; and/or 8.) Failed previous fusions.

Nota Bene: This device system is intended for anterior cervical intervertebral body fusions only.

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
CAM LOCK Plating System**

Submitted By: Life Spine, Inc.
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510(k) Contact: Randy Lewis
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Date Prepared: November 19th, 2015

Trade Name: Cam Lock Plating System

Regulation Name: 888.3060 Spinal Intervertebral Body Fixation Orthosis

Classification: Class II

Product Code: KWQ, Appliance, Fixation, Spinal Intervertebral Body

Primary Predicate: Life Spine NEO SL ACP (K070285)

Additional Predicates: Globus Providence ACP (K070775)
The Life Spine IRIS ACP (K130202)

Device Description:

The Life Spine Cam Lock Anterior Cervical Plating System consists of a variety of sizes of plates, screws, and associated instruments. Fixation is provided by bone screws inserted through the plates and into the vertebral body of the cervical spine using an anterior approach.

The Life Spine Cam Lock Anterior Cervical Plating System implant components are made from titanium alloy described by ASTM F136. Stainless steel and titanium implant components must not be used together in a construct.

Do not use any of The Life Spine Cam Lock Anterior Cervical Plating System components with the components from any other system or manufacturer.

Indications for Use of the Device:

This system is intended for anterior interbody screw fixation of the cervical spine. The system is indicated for use in the temporary stabilization of the anterior spine from C2 to T1 during the development of cervical spinal fusions in patients with: 1.) Degenerative disc disease, DDD (as defined by neck pain of discogenic origin with degeneration of disc confirmed by patient history and radiographic studies); 2.) Spondylolisthesis; 3.) Trauma (including fractures or dislocations); 4.) Spinal cord stenosis; 5.) Deformity or curvatures (i.e. kyphosis, lordosis or scoliosis); 6.) Tumors; 7.) Pseudarthrosis; and/or 8.) Failed previous fusions.

Nota Bene: This device system is intended for anterior cervical intervertebral body fusions only.

Technological Characteristics:

The Life Spine CAM LOCK Plating System is substantially equivalent to the predicate system in terms of design, materials, indications for use and sizing.

Material:

The Life Spine CAM LOCK Plating System is 6AL-4V-ELI titanium manufactured according to ASTM F136. The device is comprised of a variety of non-sterile titanium, single use components.

Performance Data:

Mechanical testing was included to demonstrate the substantial equivalency of the Life Spine CAM LOCK Plating System. The testing included static compression, dynamic compression and static torsion testing per ASTM F1717 in addition to a benchtop screw push-out test.

Conclusion:

The information presented demonstrates the substantial equivalency of the Life Spine CAM LOCK Plating System.