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

May 11, 2015

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

Re: K150126
Trade/Device Name: Life Spine Cannulated Screws
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC, HRS
Dated: April 13, 2015
Received: April 14, 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 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" (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 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

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)*
K150126

Device Name
Life Spine Cannulated Screws

Indications for Use *(Describe)*
The CANNULATED SCREW Internal Fixation System is intended to be used for alignment and stabilization of small bone fractures. Specifically:

- Fixation of small bones, such as those in the foot, ankle, wrist, elbow and hand for treatment of fractures, non-unions, or mal-unions
- Ligament reconstruction
- Osteochondritis dissecans
- Arthrodesis of the foot, ankle, wrist, elbow and hand
- Small bone osteotomies, including first metatarsal head osteotomy, metatarsal osteotomies, phalangeal osteotomies, and carpal/metacarpal osteotomies

These procedures may be indicated as a result of trauma, deformity, osteoarthritis, and rheumatoid arthritis.

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

Life Spine Cannulated Screw System

Submitted By: Life Spine
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510(k) Contact: Randy Lewis
General Manager
Life Spine
13951 S Quality Drive
Huntley, IL 60142
Telephone: 847-884-6117
Fax: 847-884-6118

Date Prepared: May 4th, 2015

Trade Name: Life Spine Cannulated Screw System

Classification: HWC, CFR 888.3040, Class II
HRS, CFR 888.3030, Class II

Primary Predicate Device: Biomet BioDrive Micro Screw (K092670)
Predicate Devices: Synthes Cannulated Screw (K963192)
ACE Medical Cortical Screw (K905048)

Device Description:

The Cannulated Screw Internal Fixation System is comprised of Cannulated Headed and Headless Screws and Hook Plates intended to align and stabilize small bone fragments around articular regions. It is fabricated and manufactured from titanium alloy (6Al-4V-ELI per ASTM F 136). Screws and hook plates offer a variety of sizes of non-sterile, single use implantable components. Longer pitched threads on the distal tip of the screw penetrates bone at a faster rate than the shorter trailing threads for headless screws, allowing interfragmentary compression as the screw is advanced and countersunk. The non-threaded portion facilitates compression of the joint surfaces through a lag technique. The low profile hook plate can provide interfragmentary compression and is well suited for areas of limited soft tissue coverage.

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

Intended Use of the Device:

The CANNULATED SCREW Internal Fixation System is intended to be used for alignment and stabilization of small bone fractures. Specifically:

- Fixation of small bones, such as those in the foot, ankle, wrist, elbow and hand for treatment of fractures, non-unions, or mal-unions
- Ligament reconstruction
- Osteochondritis dissecans
- Arthrodesis of the foot, ankle, wrist, elbow and hand
- Small bone osteotomies, including first metatarsal head osteotomy, metatarsal osteotomies, phalangeal osteotomies, and carpal/metacarpal osteotomies

These procedures may be indicated as a result of trauma, deformity, osteoarthritis, and rheumatoid arthritis.

Technological Characteristics:

The Life Spine Cannulated Screw System is substantially equivalent to the predicate systems in terms of design, materials, and indications for use.

Material:

The Life Spine Cannulated Screw System is manufactured from implantable grade titanium (Ti 6Al-4V ELI) per ASTM F136.

Performance Data:

Static and Dynamic Compression and Torsion testing in accordance with ASTM F543, Benchtop Testing, Finite Element Analysis and Engineering rationale was presented to demonstrate the substantial equivalency of the Life Spine Cannulated Screw System.

Conclusion:

The Life Spine Cannulated Screw System was shown to be substantially equivalent to the previously cleared devices in indications for use, design, function, and materials used.