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

December 21, 2017

Re: K172973
Trade/Device Name: Life Spine Foot and Ankle Plating System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: October 20, 2017
Received: November 8, 2017

Dear Randy 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.

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.

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172973

Device Name
Life Spine Foot and Ankle Plating System

Indications for Use *(Describe)*
The Life Spine Foot and Ankle Plating System is indicated for use in stabilization and fixation of fractures or osteotomies; intra and extra articular fractures, joint depression, and multifragmentary fractures; revision procedures, joint fusions, and reconstruction of the bones of small bones of the toes, feet and ankles including the distal tibia, talus, and calcaneus. The system can be used in both adult and pediatric patients.

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 Foot and Ankle Plating System

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

510(k) Contact: Randy Lewis
Life Spine
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Telephone: 847-884-6117
Fax: 847-884-6118

Date Prepared: September 22nd, 2017

Trade Name: Life Spine Foot and Ankle Plating System

Common Name: Plate, Fixation, Bone

Regulation Name: Single/multiple component metallic bone fixation appliances and accessories

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

Primary Predicate: Paragon 28 Paralock Plating System / Tuffnek Screw (K140397)

Secondary Predicate: Depuy ALPS Small Bone Locked Plating System (K101240)
Ortho Solutions Extremity Fixation Implants for osteosynthesis (K111678)
Life Spine Opening Base Wedge (K161037)

Device Description:

The Life Spine Foot and Ankle Plating System is system of plates and screws for fixation and reconstruction of the foot and ankle. The implant is fabricated and manufactured from the following:

1) Titanium (Ti 6A1-4V ELI)
2) Stainless Steel (316L)

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

Indications for Use of the Device:

The Life Spine Foot and Ankle Plating System is indicated for use in stabilization and fixation of fractures or osteotomies; intra and extra articular fractures, joint depression, and multi-fragmentary fractures; revision procedures, joint fusion and reconstructions of small bones of the toes, feet, and ankles including the distal tibia, talus, and calcaneus. The system can be used in both adult and pediatric patients.

Technological Characteristics:
The Life Spine Foot and Ankle Plating System are comparable in design and technological characteristics to one or more predicate devices. All plates utilize a plurality of screw holes to fixate the plate to bone using screws.

Material:
The Life Spine Foot and Ankle Plating System is Ti-6AL-4V-ELI titanium manufactured according to ASTM F136 and Stainless Steel 316L manufactured according to ASTM F138. Devices are single use implants.

Performance Data:
Finite Element Analysis, Engineering Rationale and Bench Top Validations were included to demonstrate the substantial equivalency of the Life Spine Foot and Ankle Plating System with respect to: torsional strength, bending strength and axial pullout.

Conclusion:
The information presented demonstrates the substantial equivalency of the Life Spine Foot and Ankle Plating System.