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

February 1, 2017

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

Re: K161279
Trade/Device Name: Life Spine Metatarsal Hemi Implant
Regulation Number: 21 CFR 888.3730
Regulation Name: Toe Joint Phalangeal (Hemi-Toe) Polymer Prosthesis
Regulatory Class: Class II
Product Code: KWD
Dated: January 5, 2017
Received: January 6, 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.

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

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)*
K161279

Device Name
The Life Spine Metatarsal Hemi Implant

Indications for Use *(Describe)*
The Life Spine Metatarsal Hemi Implant for the metatarsophalangeal joint for use in the treatment of patients with degenerative and post-traumatic arthritis in the metatarsal joint in the presence of good bone stock along with the following clinical conditions: hallux valgus or hallux rigidus, and an unstable or painful metatarsal/phalangeal (MTP) joint. The device is a single use implant intended to be used with bone cement.

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

The Life Spine Metatarsal Hemi Implant

Submitted By: Life Spine
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Telephone: 847-884-6117
Fax: 847-884-6118

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: January 24th, 2017

Trade Name: **The Life Spine Metatarsal Hemi Implant**

Common Name: MTP Hemi-Toe Prosthesis

Classification: KWD, CFR 888.3730, Class II

Predicate Device: Solana Surgical Metatarsal Decompression Implant (K090127)

Additional Predicate: Osteolink Metatarsal Resurfacing Implant (K081876)

Device Description:

The Life Spine Metatarsal Hemi Implant is an implant that has a tapered stem and a rounded head. The tapered stem allows for the implant to be fixated into the 1st metatarsal. The rounded head resurfaces the metatarsal head in the metatarso-phalangeal joint.

1) Cobalt Chrome Molybdenum Alloy (Co-28Cr-6Mo)

All implants are intended for single use only and should not be reused under any circumstances. **Do not use any of the The Life Spine Metatarsal Hemi Implant components with components from any other system or manufacturer. The Hemi Metatarsal Head Resurfacing System components should never be reused under any circumstances.**

Indications for Use:

The Life Spine Metatarsal Hemi Implant for the metatarsophalangeal joint for use in the treatment of patients with degenerative and post-traumatic arthritis in the metatarsal joint in the presence of good bone stock along with the following clinical conditions: hallux valgus or hallux rigidus, and an unstable or painful metatarsal/phalangeal (MTP) joint. The device is a single use implant intended to be used with bone cement.

Technological Characteristics:

The Life Spine Metatarsal Hemi Implant is substantially equivalent to the predicate systems in terms of design, materials, and indications for use.

Material:

The Life Spine Metatarsal Hemi Implant is manufactured from Cobalt Chrome Molybdenum Alloy (Co-28Cr-6Mo).

Performance Data:

Finite Element Analysis, bench testing (static and dynamic) as well as engineering rationale was presented to demonstrate the substantial equivalency of The Life Spine Metatarsal Hemi Implant.

Conclusion:

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