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

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

August 1, 2016

Re: K153065
Trade/Device Name: The Hammertoe Correction System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: May 27, 2016
Received: May 31, 2016

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 Parts 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)*
K153065

Device Name
The Hammertoe Correction System

Indications for Use *(Describe)*

The Life Spine HAMMERTOE Correction System is indicated for small bone reconstruction limited to inter-digital repair and fusion of the lesser toes.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary
Hammertoe Correction System

Submitted By: Life Spine, Inc.
13951 S. Quality Drive
Huntley, IL 60142
Telephone: 847-884-6117
Fax: 847-884-6118

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

Date Prepared: June 27th, 2016

Trade Name: Hammertoe Correction System

Regulation Name: Smooth or Threaded Metallic Bone Fixation Fastener

Classification: HWC, CFR 888.3040, Class II

Primary Predicate: Arthrex BioPin (K050259)
Life Spine Cannulated Screws (K150126)

Device Description:

The Hammertoe Correction System is an implant with dual threaded design and is inserted between the proximal and middle phalanges, so the opposing threads fixate on the phalangeal canal of the toe and compress the joint. The implant is fabricated and manufactured from Titanium (Ti 6A1-4V ELI)

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

Indications for Use of the Device:

The Hammertoe Correction System is indicated for small bone reconstruction limited to inter-digital repair and fusion of the lesser toes.

Technological Characteristics:
The Hammertoe Correction System is substantially equivalent to the predicate system in terms of design, indications for use and sizing.

Material:
The Hammertoe Correction System is 6AL-4V-ELI titanium manufactured according to ASTM F136. The device is comprised of non-sterile titanium, single use components.

Performance Data:
Finite Element Analysis, Custom Shear Testing and Bench Top Validations were included to demonstrate the substantial equivalency of the Life Spine Hammertoe Correction System.

Conclusion:
The information presented demonstrates the substantial equivalency of the Hammertoe Correction System.