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

December 14, 2017

Re: K173286
Trade/Device Name: Cannulated Screw Internal Fixation System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: October 3, 2017
Received: October 16, 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)*
K173286

Device Name
Cannulated Screw Internal Fixation System

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.

510(k) Summary
Cannulated Screw Internal Fixation System

Submitted By: Life Spine, Inc.
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510(k) Contact: Randy Lewis
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Date Prepared: October 3rd, 2017

Trade Name: Cannulated Screw Internal Fixation System

Regulation Name: Smooth or Threaded Metallic Bone Fixation Fastener

Common Name: Screw, Fixation, Bone

Classification: HWC, CFR 888.3040, Class II

Primary Predicate: BioPro Cannulated Go-Ez Screws K081149

Secondary Predicate: Vilex Small Headless Screw K014154
Biomet Biodrive Micro Screw System K092670

Reference Device: Life Spine Cannulated Screws K150126

Device Description:

The Life Spine Cannulated Screw Internal Fixation System is comprised of Cannulated Headed and Headless Screws intended to align and stabilize small bone fragments around articular regions. It is fabricated and manufactured from titanium alloy (Ti 6Al-4V-ELI per ASTM F 136). Screws 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.

All implants are provided non-sterile and 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.**

Indications for 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 Cannulated Screw Internal Fixation System is substantially equivalent to the predicate system in terms of design, indications for use and sizing.

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

Performance Data:
Mechanical testing according to ASTM F543 including Static Axial Pull-Out & Static Torsion was presented to demonstrate substantial equivalence of the Cannulated Screw Internal Fixation System.

Conclusion:
The information presented demonstrates substantial equivalence of the Cannulated Screw Internal Fixation System.