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

March 24, 2015

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

Re: K150368
Trade/Device Name: Tarsa-Link Wedge Fixation 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: February 20, 2015
Received: February 23, 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,

Lori A. Wiggins -S

for
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)*
K150368

Device Name
The Tarsa-Link Wedge Fixation System

Indications for Use *(Describe)*
The Tarsa-Link Wedge Fixation and screws are intended to be used for internal bone fixation for bone fractures, fusions, or osteotomies in the ankle and foot, such as:

- Opening wedge osteotomies of Hallux Valgus
- Evans lengthening osteotomies
- Metatarsal/cuneiform arthrodesis

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

Tarsa-Link Wedge Fixation System

Submitted By:
Life Spine
13951 S. Quality Drive
Huntley, IL 60142
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: February 11th, 2015

Trade Name: Tarsa-Link Wedge Fixation System

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

Predicate Device: Pro-Link Bone Wedge (K141905)

Device Description:

The TARSA-LINK Stand-Alone Wedge Fixation System is intended to be used for internal bone fixation for bone fractures, fusions, or osteotomies in the ankle and foot. The implant is available in a range of sizes and footprints to suit the individual anatomical conditions of the patient. Additionally, the wedge is fabricated and manufactured with two different materials:
1) Polyetheretherketone (PEEK) with tantalum markers and titanium pins (Ti 6Al-4V ELI).
2) Titanium (Ti 6Al-4V ELI).
The implant is hollow to permit packing with autogenous bone graft to help fusion. The implant has two pockets to permit placement of titanium bone screws (Ti 6Al-4V ELI) through the wedge to provide internal fixation.

All implants are intended for single use only and should not be reused under any circumstances. **Do not use any of the TARSA-LINK Stand-Alone Wedge Fixation System components with components from any other system or manufacturer. The TARSA-LINK Stand-Alone Wedge Fixation System components should never be reused under any circumstances.**

Intended Use of the Device:

The Tarsa-Link Wedge Fixation and screws are intended to be used for internal bone fixation for bone fractures, fusions, or osteotomies in the ankle and foot, such as:

- Opening wedge osteotomies of Hallux Valgus
- Evans lengthening osteotomies
- Metatarsal/cuneiform arthrodesis

Technological Characteristics:

The Tarsa-Link Wedge Fixation System is substantially equivalent to the predicate systems in terms of design, materials, and indications for use.

Material:

The Tarsa-Link Wedge Fixation System is manufactured from either implantable grade Polyetheretherketone (PEEK) per ASTM F2026 or Titanium (Ti 6Al-4V ELI) per ASTM F136. The device incorporates tantalum markers per ASTM F560, and implantable grade titanium (Ti 6Al-4V ELI) per ASTM F136.

Performance Data:

Benchtop testing and Finite Element Analysis was presented to demonstrate the substantial equivalency of the Tarsa-Link Wedge Fixation System.

Conclusion:

The Tarsa-Link Wedge Fixation System was shown to be substantially equivalent to the previously cleared devices in indications for use, design, function, and materials used.