



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 23, 2016

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

Re: K160169

Trade/Device Name: The Life Spine Subtalar Implant System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: February 24, 2016
Received: March 25, 2016

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 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,


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

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

Indications for Use

510(k) Number (if known)

K160169

Device Name

The Life Spine Subtalar Implant System

Indications for Use (Describe)

The LIFE SPINE Subtalar implant is indicated for use in the treatment of the hyperpronated foot and stabilization of the subtalar joint. It is designed to block forward, downward and medial displacement of the talus, thus allowing normal subtalar joint motion but blocking excessive pronation and the resulting sequela.

The LIFE SPINE Subtalar implants are intended for single use only.

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 Subtalar Implant System**

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510(k) Contact: Randy Lewis
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Date Prepared: June 22nd, 2016

Common Name: Subtalar Arthroereisis Implant

Trade Name: The LIFE SPINE Subtalar Implant System

Classification: HWC, CFR 888.3040, Class II

Primary Predicate Device: Metasurg Subtalar Implant (K070441)

Additional Predicates: Graham Medical HyProCure (K042030)

Device Description:

The LIFE SPINE Subtalar Implant System is a one piece titanium implant for treating hyperpronation of the foot. The system includes instruments (trial sizers, k-wires, and driver) to facilitate placement of the implant. Implants are manufactured from titanium alloy (Ti 6Al-4V ELI).

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

Intended Use of the Device:

The LIFE SPINE Subtalar implant is indicated for use in the treatment of the hyperpronated foot and stabilization of the subtalar joint. It is designed to block forward, downward and medial displacement of the talus, thus allowing normal subtalar joint motion but blocking excessive pronation and the resulting sequela.

The LIFE SPINE Subtalar implants are intended for single use only.

Technological Characteristics:

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

Material:

The Life Spine Subtalar Implant System is manufactured from implantable grade titanium (Ti 6Al-4V ELI) per ASTM F136.

Performance Data:

Engineering rationale was presented to demonstrate the substantial equivalency of the Life Spine Subtalar Implant System.

Conclusion:

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