September 7, 2018

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

Re: K173883
Trade/Device Name: External 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: KTT
Dated: August 10, 2018
Received: August 13, 2018

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 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,

Peter G. Allen -S
2018.09.07 13:07:38 -04'00'

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)*
K173883

Device Name
External Fixation System

Indications for Use *(Describe)*
The Life Spine External Fixation System is intended for Adults:

Fusion of the foot including:
Triple arthrodesis
Isolated hindfoot arthrodesis
Midfoot arthrodesis
Joints involved include tibiotalar, subtalar, talonavicular, calcaneocuboid, pantalar, tibio-talocalcaneus, naviculocuneiform, metatarsal cuneiform (first, second, third - e.g. Lapidus, MT), metatarsal cuboid

Treatment of fractures including:
Treatment of LisFranc fracture/dislocations in diabetic and Charcot neuropathy patient
Fractures and/or comminuted fractures (open or closed) of the calcaneus, talus, cuboid, navicular, cuneiforms, and/or metatarsals (including jones fractures), ankle and distal tibia
Additional fixation adjunct to internal fixation of the distal tibia, calcaneus, talus, navicular, cuboid, cuneiforms, and/or metatarsals in patients with significant comorbidities (i.e. diabetes) that may preclude use of isolated internal fixation

Reconstruction of deformities including:
Neuropathic deformities
Charcot reconstruction with or without corrective osteotomies
Diabetic Charcot Reconstruction
Prevention and treatment of contracture of joints and tendons in equinus

Treatment of infection unions, nonunions, or malunions

Offloading and or immobilization of ulcers and/or wounds of the foot or ankle

Stabilization associated with tendon or ligament surgeries. Tendon lengthening, repairs, and transfers both deep and or superficial around the foot and ankle including posterior tibial , tibialis anterior, flexor digitorum longus, achilles, flexor hallucis longus, peroneus longus, extensor hallucis longus, extensor digitorum longus

Tumor and neoplasm resection and reconstruction

Stabilization associated with rotation flaps, free flaps, muscle flaps, advancement flaps, fasciocutaneous flap, split thickness skin grafting, biological graft alternatives.

Pseudoarthrosis or non-unions of long bones.

Correction of bony or soft tissue deformities
Correction of segmental or nonsegmental bony or soft tissue defects
Use on long bones including tibia and fibula
Use with or without IM nail in the ankle in Charcot patients

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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K173883

# 510(k) Summary
## External Fixation System


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


**Date Prepared:** December 18th, 2017

**Trade Name:** External Fixation System

**Regulation Name:** Screw, Fixation, Bone

**Classification:** KTT, CFR 888.3030, Class II

**Primary Predicate:** Wright Medical Salvation External Fixation System (K162033)

**Secondary Predicate:** Orthofix True Lock Ring Fixation System (K170650)
Vilex Static Stabilization System (K151881)
Stryker Hoffman External Fixation (K122284)

**Device Description:**
The Life Spine External Fixation System is a component system of rings, struts, threaded rods, pins, wires and connectors intended to be used as a means to stabilize bone segments for indications within the foot and ankle. The External Fixture system is fabricated of both Radel, Stainless Steel (316L) and Aluminum. The implant components are fabricated and manufactured from the following:

1) Stainless Steel (316L)

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

**Indications for Use of the Device**:
The Life Spine External Fixation System is intended for Adults:

Fusion of the foot including:
Triple arthrodesis
Isolated hindfoot arthrodesis
Midfoot arthrodesis
Joints involved include tibiotalar, subtalar, talonavicular, calcaneocuboid, pantalar, tibio-talocalcaneus, naviculocuneiform, metatarsal cuneiform (first, second, third - e.g. Lapidus, MT), metatarsal cuboid

Treatment of fractures including:
Treatment of LisFranc fracture/dislocations in diabetic and Charcot neuropathy patient
Fractures and/or comminuted fractures (open or closed) of the calcaneus, talus, cuboid, navicular, cuneiforms, and/or metatarsals (including jones fractures), ankle and distal tibia
Additional fixation adjunct to internal fixation of the distal tibia, calcaneus, talus, navicular, cuboid, cuneiforms, and/or metatarsals in patients with significant comorbidities (i.e. diabetes) that may preclude use of isolated internal fixation

Reconstruction of deformities including:
Neuropathic deformities
Charcot reconstruction with or without corrective osteotomies
Diabetic Charcot Reconstruction
Prevention and treatment of contracture of joints and tendons in equinus

Treatment of infection unions, nonunions, or malunions

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Stabilization associated with tendon or ligament surgeries. Tendon lengthening, repairs, and transfers both deep and or superficial around the foot and ankle including posterior tibial , tibialis anterior, flexor digitorum longus, achilles, flexor hallucis longus, peroneus longus, extensor hallucis longus, extensor digitorum longus

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Correction of bony or soft tissue deformities
Correction of segmental or nonsegmental bony or soft tissue defects
Use on long bones including tibia and fibula
Use with or without IM nail in the ankle in Charcot patients

**Technological Characteristics:**
The External Fixation System is substantially equivalent to the predicate system in terms of geometry, design, indications for use, and sizing. Both systems include similar struts, rods, and rings.

**Material:**
The External Fixation System is comprised of Stainless Steel, Radel and Aluminum. The implant is Stainless Steel (316L) manufactured according to ASTM F138. The implant device is comprised of non-sterile Stainless Steel and is a single use component.

**Performance Data:**
Mechanical testing according to ASTM F1541 including Static and Dynamic Compressions, Dynamic Axial Compression Testing, Static Torsion Testing and Static 4-point Bending was presented to demonstrate the substantial equivalency of the External Fixation System.

**Conclusion:**
The information presented demonstrates the substantial equivalency of the External Fixation System.