September 29, 2022

Life Spine, Inc.
Angela Batker
RA/QA Manager
13951 S. Quality Drive
Huntley, Illinois 60142

Re: K213417
Trade/Device Name: Ghost Spacer System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: August 25, 2022
Received: September 2, 2022

Dear Angela Batker:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Brent Showalter, Ph.D.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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)*
K213417

Device Name
Ghost Spacer System

Indications for Use *(Describe)*
The Ghost Spacer System is intended for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels (L2-S1). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. DDD patients may also have up to Grade 1 spondylolisthesis at the involved level(s). It is to be used in patients who have had at least six months of non-operative treatment. This device is intended to be used with autograft bone graft and/or allogeneic bone graft composed of cancellous and/or corticocancellous bone and a supplemental internal spinal fixation system (e.g., pedicle screw or anterolateral plating system) that is cleared for use in the lumbosacral spine.

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
Ghost Spacer System

Submitted By: Life Spine, Inc.
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Telephone: 847-884-6117
Fax: 847-884-6118

510(k) Contact: Angela Batker
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Telephone: 847-884-6117
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Date Prepared: September 27, 2021

Trade Name: Life Spine Ghost Spacer System

Common Name: Intervertebral Body Fusion Device

Classification: MAX, 21 CFR 888.3080, Class II

Primary Predicate: Life Spine Plateau (K080411 & K111569)

Secondary Predicate: Life Spine Plateau-A Ti (K201500)
Life Spine ProLift Expandable Spacer System (K190488)
Life Spine Pro Lift Post-Pack (K173182)
ChoiceSpine's Tiger Shark Spacer System (K172816)

Device Description:

The Ghost Spacer System consists of implants made of titanium alloy (Ti-6Al-4V ELI per ASTM F3001). The spacers have a basic rectangular shape, a hollow center for placement of autograft bone graft and/or allogeneic bone composed of cancellous and/or corticocancellous bone to help promote fusion and a smooth bullet shaped distal surface. They are available in an assortment of height, length and anteroposterior angulation combinations to accommodate many different anatomic requirements. The implants are delivered via a posterior, transforaminal, lateral or anterior approach. The devices are manufactured using the Electron Beam Melting (EBM) additive manufacturing method. All implants are intended for single use only and should not be reused under any circumstances. **Do not use any of the GHOST Spacer System components with components from any other system or manufacturer. The GHOST Spacer System components should never be reused under any circumstances.**

Intended Use of the Device:

The GHOST Spacer System is intended for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels (L2-S1). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. DDD patients may also have up to Grade 1 spondylolisthesis at the involved level(s). It is to be used in patients who have had at least six months of non-operative treatment. This device is intended to be used with autograft bone graft and/or allogeneic bone graft composed of cancellous and/or corticocancellous bone and a supplemental internal spinal fixation system (e.g., pedicle screw or anterolateral plating system) that is cleared for use in the lumbosacral spine.

Technological Characteristics:

The Life Spine Ghost Spacer System is substantially equivalent to the predicate systems in terms of design, indications for use and sizing.

Material:

This submission seeks clearance of a device made from implant grade (Ti-6AL-4V) Titanium alloy according to ASTM F3001.

Performance Data:

Testing completed according to ASTM F2077 included Static and Dynamic Axial Compression & Compressive Shear Testing and Static subsidence testing to ASTM F2267 was presented to demonstrate the substantial equivalency of the Life Spine Plateau (K080411 & K111569).

Substantial Equivalence:

The Life Spine Ghost Spacer System was shown to be substantially equivalent to the predicate devices in indications for use, design, function, materials used and mechanical performance.

Conclusion:

The information presented demonstrates the substantial equivalency of The Life Spine Ghost Spacer System.