December 3, 2021

LESspine Innovations
% Mr. Justin Eggleton
VP, Spine Regulatory Affairs
MCRA, LLC
803 7th Street NW
Washington, District of Columbia 20141

Re: K213266
Trade/Device Name: Inspan® ScrewLES® Fusion System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal Interlaminal Fixation Orthosis
Regulatory Class: Class II
Product Code: PEK
Dated: September 30, 2021
Received: September 30, 2021

Dear Mr. Eggleton:

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,

for

Colin O'Neill, M.B.E.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213266

Device Name
Inspan® ScrewLES® Fusion System

Indications for Use *(Describe)*
The Inspan ScrewLES Fusion System is a posterior non-pedicle supplemental fixation system intended for use in the non-cervical spine (T1-S1). It is intended for plate fixation/attachment to the spinous process for the purpose of achieving supplemental fusion for the following indications: spondylolisthesis, trauma (fracture or dislocation), tumor, degenerative disc disease (defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies), or lumbar spinal stenosis. The device is intended for use with bone graft material and is not intended for stand-alone use.

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

Device Trade Name: Inspan® ScrewLES® Fusion

Manufacturer:
LESspine Innovations
350 Main Street, 2nd Floor
Malden, MA 02148, USA

Contact:
John Sullivan
VP, Global Quality & Regulatory
LESspine Innovations
350 Main Street, 2nd Floor
Malden, MA 02148, USA
Email: johnsullivan@kicventures.com

Date Prepared: November 24, 2021

Classifications: Interlaminal spinal fixation orthosis (21 CFR §888.3050)

Class: II

Product Code: PEK

Indications for Use:
The Inspan ScrewLES Fusion System is a posterior non-pedicle supplemental fixation system intended for use in the non-cervical spine (T1-S1). It is intended for plate fixation/attachment to the spinous process for the purpose of achieving supplemental fusion for the following indications: spondylolisthesis, trauma (fracture or dislocation), tumor, degenerative disc disease (defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies), or lumbar spinal stenosis. The device is intended for use with bone graft material and is not intended for stand-alone use.

Device Description:
The Inspan ScrewLES Fusion System, previously cleared (under K102020) and marketed as, "Vega™ SPAN™ Spinous Process Plate System", consists of plates of varying length and hub diameters, set screws, and instruments required for implantation. Spikes are present on the sides of the plate that interface with the spinous process to restrain the plate from rotating post-operatively. The device is offered with varying lengths and hub diameters to accommodate anatomical needs. Set screws are used to secure the two sides of the device into the final compressed and implanted construct.

System components are supplied non-sterile, are single use and are fabricated from titanium alloy (Ti-6AI-4V ELI) that conforms to ASTM F 136.

Primary Predicate Device:
The subject device, Inspan ScrewLES Fusion System has been demonstrated to be substantially equivalent to the primary predicate device.

Table 1: Primary Predicate Device

Subject Device	Primary Predicate		
	Device Name	Manufacturer	K-Number
Inspan ScrewLES Fusion System	Vega™ SPAN™ Spinous Process Plate System *	SpineFrontier, Inc.**	K102020

*Since the original 510(k) clearance, Vega Span has been rebranded as Inspan ScrewLES Fusion System
**Since the original 510(k) clearance, SpineFrontier is now operating as, "LESspine, LLC."

Non-Clinical Performance Testing Summary:
Pre-clinical testing data submitted, referenced or relied upon to demonstrate substantial equivalence includes biocompatibility, sterilization, and non-clinical testing data.

Clinical Performance Testing Summary:
A retrospective review of prospectively collected data was performed by Chin et al. (2020). In total, 56 patients received the subject device for degenerative disc disease with lumbar spinal stenosis where the authors reported statistically significant improvements in patients receiving the subject device for lumbar spinal stenosis at 24 months postoperatively for VAS back pain and ODI.

Substantial Equivalence:
The subject device was demonstrated to be substantially equivalent to the predicate devices cited in the passage above with respect to indications, design, materials, function, manufacturing, and performance.

Conclusion:
The subject device is substantially equivalent to the cited predicate device with respect to indications for use, design, function, materials, and performance. Additionally, the provided clinical data related to the subject device, supports this traditional 510(k).