September 28, 2023

LESspine Innovations
℅ Nathan Wright
Engineer & Regulatory Specialist
Empirical Technologies
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K232605
Trade/Device Name: Sacrix® Sacroiliac Joint Fusion Device System, Inspan® ScrewLES Fusion System, Invue® MAX™ + Invue Inset Anterior Cervical Plate System, and FacetFuse® Screw Fixation System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: OUR, PEK, KWQ, MRW
Dated: August 25, 2023
Received: August 28, 2023

Dear Nathan Wright:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Colin O'neill -S

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.

Submission Number *(if known)*

K232605

Device Name

Sacrix® Sacroiliac Joint Fusion Device System, Inspan® ScrewLES Fusion System, Invue® MAX™ + Invue Inset Anterior Cervical Plate System, and FacetFuse® Screw Fixation System

Indications for Use *(Describe)*

The Sacrix® Sacroiliac Joint Fusion Device System is intended for fusion of the sacroiliac joint for conditions including sacroiliac joint disruptions and degenerative sacroiliitis.

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, or 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.

The Invue® MAX™ + Invue Inset Anterior Cervical Plate System is intended for anterior spine fixation for use in providing temporary stabilization during the development of cervical spinal fusions. The levels of treatment range from C2 to T1. Indications include symptomatic cervical spondylolisthesis, trauma; (fracture or dislocation), spinal stenosis, deformities or curvatures (scoliosis, kyphosis and or lordosis), tumor, pseudloarthrosis, degenerative disc disease (defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies), and re-operation for failed fusion or instability following surgery for above indications.

The FacetFuse® Screw Fixation System is intended to stabilize the spine as an aid to fusion by transfacet fixation. The subject device is indicated for posterior surgical treatment of any or all of the following at the L1 to S1 (inclusive) spinal levels including: 1) Trauma, including spinal fractures and/or dislocations; 2) Spondylolisthesis; 3) Spondylolysis; 4) Pseudoarthrosis or failed previous fusions which are symptomatic or which may cause secondary instability or deformity; 5) Degenerative diseases which include: (a) degenerative disc disease (DDD) as defined by neck and/or back pain of discogenic origin as confirmed by patient history with degeneration of the disc as confirmed by radiographic studies and/or (b) degenerative disease of the facets with pain and/or instability on plain flexion and extension lateral radiographs where there is movement of the vertebral bodies relative to each other of more than 4mm.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) SUMMARY

Submitter's Name:	LESspine Innovations
Submitter's Address:	350 Main Street Malden, Massachusetts 02148
Submitter's Telephone:	978-232-3990
Contact Person:	Nathan Wright MS, RAC Empirical Technologies 719-351-0248 nwright@empiricaltech.com
Date Summary was Prepared:	August 25, 2023
Trade or Proprietary Name:	Sacrix® Sacroiliac Joint Fusion Device System
Device Classification Name:	Sacroiliac Joint Fixation
Classification & Regulation #:	Class II per 21 CFR §888.3040
Product Code:	OUR
Trade or Proprietary Name:	Inspan® ScrewLES Fusion System
Device Classification Name:	Spinous Process Plate
Classification & Regulation #:	Class II per 21 CFR §888.3050
Product Code:	PEK
Trade or Proprietary Name:	Invue® MAX™ + Invue Inset Anterior Cervical Plate System
Device Classification Name:	Appliance, Fixation, Spinal Intervertebral Body
Classification & Regulation #:	Class II per 21 CFR §888.3060
Product Code:	KWQ
Trade or Proprietary Name:	FacetFuse® Screw Fixation System
Device Classification Name:	System, Facet Screw Spinal Device
Classification & Regulation #:	Unclassified
Product Code:	MRW
Classification Panel:	Orthopedic – Spinal (DHT6B)

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Sacrix® Sacroiliac Joint Fusion Device System implants consist of Solid and Fenestrated Screws. Solid and Fenestrated Screws are available in varying diameters and lengths. Solid and Fenestrated Screws are fabricated from medical grade titanium alloy, Ti-6AI-4V ELI per ASTM F136. Solid and Fenestrated Screws have a cannulated core to allow packing of allograft or autograft material. Solid Screws have a solid outer wall, while Fenestrated Screws have fenestrations on the outer wall.

The Inspan® ScrewLES Fusion System consists of a variety of sizes of plates, set screws, and associated instruments. The plates are offered in five hub diameters (8 mm to 20 mm in 2 mm increments) and five wing length configurations (35 mm to 47 mm in 2 mm increments). The device height (measured from the base of the central hub to the top of the wing) is fixed across all configurations at 18.85 mm for InSpan® and 13.89 mm for InSpan® Slim. Spikes are present on the sides of the plate that interface with the spinous process to restrain the

plate from rotating post-operatively. The components of the Inpan® ScrewLES Fusion System are fabricated from medical grade titanium alloy Ti-6AI-4V ELI per ASTM F136.

The Invue® MAX™ + Invue Inset Anterior Cervical Plate System consists of a variety of shapes and sizes of plates, screws, and the associated instruments. The plates are available in four levels to accommodate one to four levels of fixation. The one level plates have lengths ranging from 17 mm to 35 mm in 2 mm increments, two level plates range from 33 mm to 55 mm in 2 mm increments, three level plates range from 48 mm to 78 mm in 3 mm increments, and the four-level plates range from 61 mm to 109 mm in 4 mm increments. A lock is integrated in the plate and screw to secure the screw from backout. Ø4.2 mm self-drilling or self-drilling screws and Ø4.5 mm self-tapping screws are offered. All screws are offered in lengths of 12 mm, 14 mm, 16 mm, 18 mm, and 20 mm. The Invue® MAX™ + Invue Inset Anterior Cervical Plate System components are single use and are fabricated from titanium alloy Ti-6AI-4V ELI per ASTM F136.

The FacetFuse® Screw Fixation System is designed to provide bilateral, transfacet fixation of the spinal facet joint in the lumbar spine. The FacetFuse® Screw Fixation System offers partially threaded and fully threaded screws. The partially threaded screws are available in Ø4.5 mm to Ø6.0 mm diameter screw (in 0.5 mm increments) offered in lengths of 25 mm to 50 mm (in 5 mm increments). The fully threaded screws are available in diameters Ø4.5 mm and Ø5.0 mm in lengths from 20 mm to 50 mm in 5 mm increments. The device is fabricated from titanium alloy Ti-6Al-4V ELI per ASTM F136. The devices are offered with a built in washer or without a washer. The washers are intended to increase the load bearing area of the screw in contact with the bone. These washers are designed to angulate about the head of the bone screws to provide optimal bony contact over a range of screw trajectories.

The purpose of this submission is to offer sterile packaged options of each implant.

INDICATIONS FOR USE

The Sacrix® Sacroiliac Joint Fusion Device System is intended for fusion of the sacroiliac joint for conditions including sacroiliac joint disruptions and degenerative sacroiliitis.

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, or 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.

The Invue® MAX™ + Invue Inset Anterior Cervical Plate System is intended for anterior spine fixation for use in providing temporary stabilization during the development of cervical spinal fusions. The levels of treatment range from C2 to T1. Indications include symptomatic cervical spondylolisthesis, trauma; (fracture or dislocation), spinal stenosis, deformities or curvatures (scoliosis, kyphosis and or lordosis), tumor, pseudoarthrosis, degenerative disc disease (defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies), and re-operation for failed fusion or instability following surgery for above indications.

The FacetFuse® Screw Fixation System is intended to stabilize the spine as an aid to fusion by transfacet fixation. The subject device is indicated for posterior surgical treatment of any or all of the following at the L1 to S1 (inclusive) spinal levels including: 1) Trauma, including spinal fractures and/or dislocations; 2) Spondylolisthesis; 3) Spondylolysis; 4) Pseudoarthrosis or failed previous fusions which are symptomatic or which may cause secondary instability or deformity; 5) Degenerative diseases which include: (a) degenerative disc disease (DDD) as defined by neck and/or back pain of discogenic origin as confirmed by patient history with degeneration of the disc as confirmed by radiographic studies and/or (b) degenerative disease of the facets with pain and/or instability on plain flexion and extension lateral radiographs where there is movement of the vertebral bodies relative to each other of more than 4mm.

TECHNOLOGICAL CHARACTERISTICS

The subject and predicate devices have the same technological characteristics and the minor differences do not raise any new issues of safety and effectiveness. Specifically, the following characteristics are the same between the subject and predicates:

- Indications for Use
- Materials of manufacture
- Structural Support Mechanisms
- Design Features

The sterile packaging was validated to mitigate any risk of the change in sterilization method.

Sacrix® Sacroiliac Joint Fusion System Device Predicate Devices

510k Number	Trade or Proprietary or Model Name	Manufacturer	Predicate Type
K150017	Sacrix® Sacroiliac Joint Fusion Device System	LESspine Innovations	Primary
K021932	Synthes 6.5 mm Cannulated Screw	Synthes (USA)	Additional
K223708	Entasis 3D Dual-Lead Sacroiliac Implant System	CoreLink, LLC	Additional

Inspan® ScrewLES Fusion System Predicate Devices

510k Number	Trade or Proprietary or Model Name	Manufacturer	Predicate Type
K213266	InSpan ScrewLES Fusion System	LESspine Innovations	Primary

Invue® MAX™ + Invue Inset Anterior Cervical Plate System Predicate Devices

510k Number	Trade or Proprietary or Model Name	Manufacturer	Predicate Type
K121060	SpineFrontier Indus™	LESspine Innovation	Primary
K093776	Indus™ Anterior Cervical Plate System	LESspine Innovation	Additional
K163104	Terrace™ Anterior Cervical Plate System	CoreLink, LLC	Additional

FacetFuse® Screw Fixation System Predicate Devices

510k Number	Trade or Proprietary or Model Name	Manufacturer	Predicate Type
K071420	Chameleon FacetFuse MIS Screw System	LESspine Innovation	Primary
K211855	Ion Facet Screw System	SurGenTec, LLC	Additional
K131471	Facet Fixx™	Nexxt Spine	Additional
K012773	Discovery Facet Screw Fixation System	DePuy AcroMed™, Inc.	Additional

PERFORMANCE DATA

The Sacrix® Sacroiliac Joint Fusion Device System has previously been tested under its previous clearance in the following test modes:

- Static axial pull out per ASTM F543
- Static three-point bending per ASTM F2193
- Dynamic three-point bending per ASTM F2193

The Inspan® ScrewLES Fusion System has previously been tested under its previous clearance in the following test modes:

- Static compression bending per ASTM F1717
- Dynamic compression bending per ASTM F1717
- Torsion testing per ASTM F1717

The Invue® MAX™ + Invue Inset Anterior Cervical Plate System has previously been tested under its previous clearance in the following test modes:

- Static compression bending per ASTM F1717
- Dynamic compression bending per ASTM F1717
- Torsion testing per ASTM F1717

The FacetFuse® Screw Fixation System has previously been tested under its previous clearance to meet the performance standards of ASTM F2193 and ASTM F543.

The results of these non-clinical tests showed that each system is substantially equivalent to legally marketed predicate devices. The changes in sterilization and packaging do not affect mechanical performance and require no additional bench testing for this submission.

CONCLUSION

The overall technology characteristics and mechanical performance data lead to the conclusion that the Sacrix® Sacroiliac Joint Fusion Device System, Inspan® ScrewLES Fusion System, Invue® MAX™ + Invue Inset Anterior Cervical Plate System, and FacetFuse® Screw Fixation System are substantially equivalent to the predicate devices.