November 13, 2018

Premia Spine Ltd.
% Janice Hogan, J.D.
Partner
Hogan Lovells US LLP
555 Thirteenth Street, Northwest
Washington, District of Columbia 20004

Re: K182598
Trade/Device Name: VersaLink™ Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: NKB
Dated: November 9, 2018
Received: November 9, 2018

Dear Ms. Hogan:

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,

Ronald P. Jean -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

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182598

Device Name
VersaLink™ Fixation System

Indications for Use *(Describe)*
The VersaLink™ Fixation System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative disc disease (DDD; defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.

The VersaLink™ Fixation System can be used in an open approach or a posterior, percutaneous approach with minimally invasive (MIS) instrumentation.

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)

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K182598
510(k) SUMMARY
Premia Spine's VersaLink™ Fixation System

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Contact Person: Mr. Ron Sacher

Date Prepared: November 6, 2018

VersaLink™ Fixation System
21 C.F.R. 888.3070 Pedicle screw spinal system, Class II.
Product codes: NKB - orthosis, spinal pedicle fixation, for degenerative disc disease

Primary Predicate
ProMIS™ Fixation System by Premia Spine Ltd. (K150380)

Intended Use / Indications for Use
The VersaLink™ Fixation System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative disc disease (DDD; defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.

The VersaLink™ Fixation System can be used in an open approach or a posterior, percutaneous approach with minimally invasive (MIS) instrumentation.

Device Description
The VersaLink™ System consists of 6 Ti-6Al-4V main parts:

1. The VersaLink rod (the Rod): a spinal fixation rod with a dedicated ring end designed to enable robust attachment to the pedicle screw head above the crossbar.
2. Ring nut: dedicated nut designed to be tightened on the Ring Set Screw and firmly fix the VersaLink™ Rod on the pedicle screw head.
3. VersaLink Ring Set Screw Torx: dedicated setscrews with double thread designed to allow attachment of the VersaLink™ Rod device to the head of the pedicle screw above the crossbar.
4. Crossbar rod: a bent rod designed to fit the average angle of the lumbar vertebra pedicles. It is horizontally attached to two pedicle screws on the same vertebra in order to reduce peak loads by better distributing the loads between the pedicle screws.
5. Polyaxial Pedicle screws
6. Torx Setscrew.

Performance Data

The VersaLink™ Fixation System was subjected to static compression, static torsion, and dynamic compression testing per ASTM F1717. All devices functioned as intended and met their acceptance criteria.

Substantial Equivalence

The VersaLink™ Fixation System and ProMIS Fixation System have the same intended use and indication for same users' population.

The subject and predicate systems are made from the same materials and are composed of the same components, including pedicle screws, fusion rods, and set screws, and are operated according to the same principals.

The subject and predicate systems have similar components, made of same materials. Both systems are based on the same pedicle screws and set screws, with identical design, diameter and length. Both systems have fusion rods with similar diameter and length. The subject and predicate systems carry similar accessories and surgical instrumentation set.

Conclusions

The subject VersaLink™ Fixation System is substantially equivalent to the cleared ProMIS™ Fixation System. The subject system has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor technological differences raise no new issues of safety or effectiveness. Performance data demonstrate that the VersaLink™ Fixation System is substantially equivalent to its predicate.