Premia Spine Ltd.
℅ Janice Hogan
Partner
Hogan Lovells US LLP
1735 Market St., 23rd Floor
Philadelphia, Pennsylvania 19103

July 7, 2023

Re: K231844
Trade/Device Name: ProMIS™ Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB
Dated: June 22, 2023
Received: June 22, 2023

Dear Janice 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/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,

Eileen Cadel -S

Digitally signed by Eileen Cadel -S
Date: 2023.07.07 14:41:37 -04'00'

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)*
K231844

Device Name
ProMIS™ Fixation System

Indications for Use *(Describe)*

The ProMIS™ 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 instabilties 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 ProMIS™ Fixation System can be used in an open approach or a posterior, percutaneous approach with minimal 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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510(k) SUMMARY

Premia Spine Ltd's ProMIS™ Fixation System

Submitter:

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Facsimile: +972-7222-81203

Contact Person: Dr. Dorit Winitz

Date Prepared: April 19, 2023

Trade Name: ProMIS™ Fixation System

21 C.F.R 888.3070 Thoracolumbosacral pedicle screw system
NKB – Class II

Primary Predicate Device

ProMIS™ Fixation System by Premia Spine Ltd (K150380)

Purpose of the Special 510(k) notice.

The ProMIS™ Fixation System is a modification to the previously cleared ProMIS™ Fixation System by Premia Spine Ltd (K150380). The changes being made in the submission include:

- Expanding the pedicle screws line to include additional screws with the following features:
    - increased polyaxiality
    - decreased tulip's profile,
    - cannulated and non-cannulated pedicle screw bodies with self-tapping flutes and tapered and rounded or self-drilling tips
- Addition of fusion rods of different lengths and tip designs
- Addition/minor modifications to Class I instruments

Indications for Use

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

Device Description

The ProMIS™ Fixation System consists of 3 main single use implanted parts:

1. ProMIS™ Fusion Rods: a straight or bent rod of various lengths.

2. Polyaxial Pedicle Screws: cannulated and non- cannulated screw bodies with self-tapping flutes and rounded or self-drilling tips, available in three diameters (5.5mm, 6.5mm, 7.5mm) with length ranging from 25 to 60, in increments of 5mm.

3. Setscrew.

All components are manufactured from Ti6Al4V per ASTM F136

Rods up to 100mm in length and the Pedicle Screws are provided sterile (gamma irradiated).

Rods exceeding 100mm are supplied non-sterile (steam/autoclave sterilization by the end user).

Performance Data

The ProMIS™ Fixation System was subjected to static torsion and dynamic compression testing per ASTM F1717.

Substantial Equivalence

The cleared and modified ProMIS Fixation Systems share the same indications for use and principles of operation and the same components, materials, manufacturing processes and sterilization methods. They also share very similar design features, with the exception of the minor modifications that do not raise different questions of safety and efficacy.

The additional screw designs were added to address different surgeons' preferences for pedicle preparation and screw insertion techniques and to enhance manufacturability. The design modifications included increased polyaxiality, decreased tulip's profile, non-cannulated and cannulated pedicle screw bodies with self-tapping flute and tapered rounded or self-drilling tip design, and additional minor changes to enhance manufacturability. The functionality and mechanical performance of the modified pedicle screws were verified in functionality and mechanical testing, demonstrating substantial equivalent performance.

A few fusion rods of different lengths and tip designs were added to the product matrix, with different combinations of standard hex, bullet and blunt tips. The added longer rods do not represent a worst-case in terms of mechanical performance. Therefore, this modification does not raise different questions of safety or effectiveness.

Conclusions

The subject ProMIS™ 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 ProMIS™ Fixation System is substantially equivalent to the previously cleared ProMIS™ Fixation System.