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

November 21, 2023

Re: K232719
Trade/Device Name: ProMIS Extension Rod System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB
Dated: September 5, 2023
Received: September 5, 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 (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,

Eileen Cadel -S
Digitally signed by Eileen Cadel -S
Date: 2023.11.21 14:34:03 -05'00'

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K232719

Device Name
ProMIS Extension Rod System

Indications for Use *(Describe)*
When used with the ProMIS Fixation System, the ProMIS Extension Rod System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion, for the treatment of the following acute and chronic instabilities or deformities of the 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 Extension Rod System is compatible with Premia Spine's Slender Tulip Polyaxial Pedicle Screws for extending the ProMIS Fixation System to a single adjacent level.

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

Premia Spine's ProMIS Extension Rod System

Submitter:

Premia Spine Ltd.
Giborey Israel 7
Ramat Poleg, Netanya, 4250407, Israel
Phone: +972-54-8080130
Facsimile: +972-7222-81203

Contact Person: Dr. Dorit Winitz.

Date Prepared: November 20, 2023

Trade Name: ProMIS Extension Rod System

21 C.F.R 888.3070 Thoracolumbosacral pedicle screw system

NKB – Class II

Predicate Devices

Primary Predicate: ProMIS™ Fixation System by Premia Spine (K231844)

Additional Predicate: Annex™ Adjacent Level System by Spine Wave (K132403)

Intended Use / Indications for Use

When used with the ProMIS Fixation System, the ProMIS Extension Rod System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion, for the treatment of the following acute and chronic instabilities or deformities of the 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 Extension Rod System is compatible with Premia Spine's Slender Tulip Polyaxial Pedicle Screws for extending ProMIS Fixation System to a single adjacent level.

Device Description

The ProMIS Extension Rod System (also referred to as PER System) is composed of a fusion rod (Turret™ Rod) with a spherical head at one end and a rod on the other end. The Turret™ Rod's end is connected to a pedicle screw at the adjacent vertebrae to be fused, while the spherical head attaches to the Tulip's head of Premia Spine's pedicle screw of the existing fusion system using a designated Set Screw and a Ring Nut.

The spherical head of the ProMIS Extension Rod System is designed to be positioned on Premia Spines' Slender Tulip Polyaxial Pedicle Screws. The Rod is available in two lengths 60 and 75 mm in a diameter of 6 mm.

All components of the ProMIS Extension Rod System are made of Titanium alloy (Ti-6Al-4V ELI per ASTM F136).

Performance Data

The ProMIS Extension Rod System was subjected to static torsion and dynamic compression testing per ASTM F1717. All devices functioned as intended and have substantially equivalent mechanical performance compared to predicate devices..

Substantial Equivalence

ProMIS Extension Rod System is substantially equivalent to other legally marketed Pedicle Screw Spinal Systems. Specifically, the ProMIS Extension Rod System is substantially equivalent to the Annex™ Adjacent Level System (K132403) and the Company's ProMIS™ Fixation System (K231844).

The ProMIS Extension Rod System shares the same general intended use and similar indications as its predicate devices. The minor differences between the ProMIS Extension Rod System and its predicate's indications are within the scope of the general intended use and do not raise new questions of safety and efficacy.

The subject and predicate systems are made from the same materials, are composed of very similar components that have equivalent functions and are operated according to the same principles. The subject and predicate systems share similar accessories and surgical instrumentation set, except for surgical instruments used for MIS procedures that are applicable for ProMIS™ Fixation System and Annex™ Adjacent Level System and not applicable for the ProMIS Extension Rod System.

Minor differences in the technological characteristics do not raise new questions of safety or efficacy. Mechanical bench testing demonstrates that the ProMIS Extension Rod System performs in a substantially equivalent manner as its predicate devices.

Conclusions

The Subject ProMIS Extension Rod System is substantially equivalent to the cleared Annex™ Adjacent Level System and ProMIS™ Fixation System with respect to the general intended use, similar indications, technological characteristics, principles of operations and performance. The minor differences raise no new issues of safety or effectiveness.