DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

February 2, 2017

Premia Spine Ltd.
% Ms. Janice M. Hogan
Partner
Hogan Lovells US LLP
1835 Market Street, 29th Floor
Philadelphia, Pennsylvania 19103

Re: K170061
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: January 6, 2017
Received: January 6, 2017

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. 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Mark N. Melkerson -S

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: January 31, 2017
See PRA Statement on last page

510(k) Number *(if known)*

K170061

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 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 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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510(k) SUMMARY

Premia Spine Ltd.'s ProMIS™ Fixation System

Submitter:

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Facsimile: 972-72-2281201
Contact Person: Vered Nitzan

Date Prepared: January 31, 2017

Trade Name: ProMIS™ Fixation System

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

Predicate Devices

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

Device Description

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

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

2. Polyaxial Pedicle screws.

3. Setscrew.

All components are manufactured from Ti6Al4V per ASTM F136.

Intended Use/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 minimally invasive (MIS) instrumentation.

Summary of Technological Characteristics

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.

The following technological differences exist between the subject and predicate devices:

- The short rods (up to 100mm) in the subject system are provided sterile by gamma irradiation, while in the predicate system they are provided non sterile and should be steam sterilized by the user. Please note the package was not altered due to this modification.
- The rods length range in the subject system is 35mm-180mm, while in the predicate system it is 40mm-180mm in length.
- Minor design change to the set-screw
- Addition of Instrumentation

Purpose of 510(k)

The purpose of this 510(k) is to modify the ProMIS™ Fixation System by the sterilization method of rods up to 100mm and to add rods with 35 mm lengths, a modified set screw, and Class I instrumentation.

Performance Data

Sterilization validation of the modified process was conducted according to ISO 11137-2:2013 by the method of substantiation of 25kGy as a sterilization dose for SAL 10^{-6} (VDmax25).

Bacterial endotoxin testing (BET) as specified in USP <85> is used for pyrogenicity testing to achieve the Endotoxin limit of <20EU/device.

Packaging validation according to ASTM D4169-16 and AAMI/ ISO 11607-1: 2006 (R) 2010, and accelerated aging study, and real time (ongoing) study, according to ASTM F1980-07 (2011) and ISO 11607-1:2006, were conducted in order to verify the integrity of the product packaging during their transportation and shelf life thus assuring product sterility (SAL 10^{-6}) and safety when the product is used.

The mechanical performance of the modified Set-Screw design was verified under functionality test demonstrating clear and smooth movements between parts and proper locking into position.

An engineering analysis was performed and demonstrated the subject components do not introduce a new worst case. Therefore, additional mechanical testing was not performed.

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.

Table 3.1. Comparison Table between the subject and predicate systems:

		Subject ProMIS™ Fixation System	Predicate ProMIS™ Fixation System (K150380)
Intended Use/ 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 minimally invasive (MIS) instrumentation.	
User Population		Skeletally mature patients	
Material		Pedicle and Set screws: Ti6Al4V Fusion Rods: Ti6Al4V	
Dimensions:		Pedicle screws: Diameter: 5.5mm-8.5mm Length: 25mm-60mm Fusion Rods: Diameter: 6mm Length: 35mm-180mm	Pedicle screws: Diameter: 5.5mm-8.5mm Length: 25mm-60mm Fusion Rods: Diameter: 6mm Length: 40mm-180mm
Design Features	**Fusion Rods**	Straight or bent with various lengths	
	Pedicle Screws	Polyaxial pedicle screws consist of a self-drilling, cannulated, threaded portion, an insert, a pedicle screw head	
	Set Screw	Includes internal slots	Does not include internal slots
Sterilization Process		• Pedicle and set screws –provided sterile by gamma irradiation • Fusion Rods up to 100mm - provided sterile by gamma irradiation • Fusion Rods longer than 100mm – provided non sterile, to be steam sterilized by user	• Pedicle and set screws –provided sterile by gamma irradiation • Fusion Rods – provided non sterile, to be steam sterilized by user
Single Use		Single use	
Shelf Life		5 years	Fusion Rods – not applicable Pedicle and Set Screws – 5 years