October 8, 2019

Premia Spine, Ltd.
% Janice Hogan
Partner
Hogan Lovells US LLP
1735 Market Street
Suite 2300
Philadelphia, Pennsylvania 19103

Re: K191854
Trade/Device Name: Premia Spine XL Instruments
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: July 10, 2019
Received: July 10, 2019

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,

Shumaya Ali, MPH
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma 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)*

K191854

Device Name

Premia Spine XL Instruments

Indications for Use *(Describe)*

Premia Spine XL Instruments are intended to be used during the preparation and placement of Premia Spine screws during surgery to assist the surgeon in precisely locating anatomical structure in either open or minimally invasive procedures.

Premia Spine XL Instruments are specifically designed for use with the Medtronic StealthStation System, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks for the anatomy.

The XL Instruments are nonsterile instruments that can be used manually. These instruments are intended to be used with the Medtronic's StealthStation Navigation System.

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.

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K191854
Premia Spine Ltd.'s XL Instruments

1. Submitter's Identification

Premia Spine Ltd.
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Israel
Phone: +972-72-228-1200
Contact Person: Ron Sacher

Date Prepared: October 7, 2019

2. Name of Device

Name of Device: XL Instruments
Common or Usual Name: XL navigation instruments
Classification: 21 CFR 882.4560
Classification Name: Stereotaxic instrument
Regulatory Class: II
Product Code: OLO
Product Code Name: Orthopedic Stereotaxic Instrument

3. Predicate and Reference Device Information

Predicate: K153442, Medtronic Navigated Reusable Instruments for Use with the StealthStation® and IPC® Powerease™ Systems

4. Device Description

The XL Instruments is comprised of seven instruments:

- Cannulated Screwdriver;
- Cannulated Pedicle AWL;
- Cannulated Pedicle Probe;
- Cannulated TAP XL 4.5, 5.5 and 6.5 mm;
- Straight Pedicle Probe.

The XL Instruments are reusable stereotaxic surgical instruments, designed to be used with the Medtronic StealthStation navigation system.

They are reusable (autoclavable) instruments, intended to be used in a sterile environment, and initially supplied non-sterile to the user and requires the user to process (i.e., clean and sterilize) the device for initial use, as well as after each use.

5. Indications for Use

Premia Spine XL Instruments are intended to be used during the preparation and placement of Premia Spine screws during surgery to assist the surgeon in precisely locating anatomical structure in either open or minimally invasive procedures.

Premia Spine XL Instruments are specifically designed for use with the Medtronic StealthStation System, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks for the anatomy.

The XL Instruments are nonsterile instruments that can be used manually. These instruments are intended to be used with the Medtronic's StealthStation Navigation System.

6. Summary of Technological Characteristics and Comparison

The clinical set-up and mode of operation of the subject device are similar to the proposed predicate (K153442).

Both the predicate and the subject devices are composed of several instruments designed to be registered and then identified by the Medtronic StealthStation to allow the surgeon using them to precisely locate anatomical structures during stereotaxic surgical procedures.

The principles of operation of the XL instruments are identical to those of the predicate.

The technical specifications of the subject and predicate devices are similar. The system features sufficiently equivalent geometries to the predicate such that the performance of the subject and predicate devices are equivalent.

Parameter	XL Instruments	Medtronic Instruments
Indication for Use	Premia Spine XL Instruments are intended to be used during the preparation and placement of Premia Spine screws during surgery to assist the surgeon in precisely locating anatomical structure in either open or minimally invasive procedures. Premia Spine XL Instruments are specifically designed for use with the Medtronic StealthStation System, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks for the anatomy. The XL Instruments are nonsterile instruments that can be used manually. These instruments are intended to be used with the Medtronic's StealthStation Navigation System.	Medtronic Navigated Reusable Instruments are intended to be used during the preparation and placement of Medtronic screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open, or minimally invasive, procedures. Medtronic Navigated Reusable Instruments are specifically designed for use with the StealthStation® System, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as a skull, a long bone, or vertebra can be identified relative to a CT or MR-based model, fluoroscopy images, or digitized landmarks of the anatomy.

Parameter	XL Instruments	Medtronic Instruments
Class	II	II
Regulation	21 CFR §882.4560	21 CFR §882.4560
Code	OLO	OLO
510k number	Subject	K153442
Environment	Surgery operating room	Surgery operating room
Prescription	Rx Prescription	Rx Prescription
Critical dimensions	Identical for Tap 4.5 mm, Tap 5.5 mm, Tap 6.5 mm, Pedicle awl, Pedicle probe; Equivalent for screwdriver	
Instrument Registration	Identical	
Instrument Calibration	Identical	
Instrument Interface	Identical	
Tracking method	Identical	
Material	Stainless steel	Stainless steel
Sterilization	To be steam sterilized before use	To be steam sterilized before use

Table VII-1: Comparison Table

7. Summary of Performance Data

Bench testing was performed per the following voluntary performance standards or FDA guidance:

- Registering and calibration of the instruments on the StealthStation testing;
- Failure mode testing;
- Interfacing of each instrument with the StealthStation testing, per ASTM F-2554;
- Equivalence of the pre-submitted geometric properties of the predicate and subject devices.

All tests met the predefined acceptance criteria.

8. Conclusions

The XL Instruments set has the same intended use and the same basic technological characteristics of the predicate device, Medtronic Navigated Reusable Instruments for Use with the StealthStation® and IPC® Powerease™ Systems. The differences of geometry between the subject and the predicate devices are supported by the comparison testing and do not raise different questions of safety and effectiveness. Performance testing has demonstrated that the XL Instruments set is as safe and effective as the predicate. Therefore, the XL Instruments set is substantially equivalent to the predicate device.