October 11, 2019

Providence Medical Technology, Inc.
Janie Mandrusov, Ph.D.
Vice President, Clinical and Regulatory Affairs
3875 Hopyard Road, Suite 300
Pleasanton, California 94588

Re: K183589
Trade/Device Name: PMT Facet Screw
Regulatory Class: Unclassified
Product Code: MRW
Dated: September 20, 2019
Received: September 20, 2019

Dear Dr. Mandrusov:

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,

Ronald P. Jean, Ph.D.
Director (Acting)
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)*
K183589

Device Name
PMT Facet Screw

Indications for Use *(Describe)*

The PMT Facet Screw is intended to stabilize the spine as an aid to fusion through bilateral immobilization of the facet joints. The screws are inserted posteriorly through the superior side of the facet, across the facet joint, and into the pedicle. The PMT Facet Screw is indicated for bilateral facet fixation, with or without bone graft, at single or multiple levels, from C2 to S1. The PMT Facet Screw is indicated for treatment of any or all of the following:
1. Pseudoarthrosis and failed previous fusion
2. Spondylolisthesis
3. Spondylolysis
4. Degenerative disc disease (DDD) as defined by neck and/or back pain of discogenic origin as confirmed by radiographic studies
5. Degeneration of the facets with instability; and
6. Fracture

The PMT Facet Screw is intended for conventional or tissue-sparing surgical placement.

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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"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

Providence Medical Technology, Inc.'s PMT Facet Screw

Date Prepared: September 20, 2019

Company: Providence Medical Technology, Inc.
3875 Hopyard Rd., Suite 300
Pleasanton, CA 94588

Contact Person: Janie Mandrusov
Phone: 415.301.3128
Facsimile: 415.923.9377

Trade Name: PMT Facet Screw

Common Name: Facet Screw

Classification Name: System, Facet Screw Spinal Device

Product Code, Class: MRW, Unclassified

Predicate Devices:

Primary Predicate: NuVasive Triad Facet Screw System (K020411, cleared 3/12/2012)

Additional Predicate: Venus Facet Screw System (K120340, cleared 10/19/12)

Indications for Use:

The PMT Facet Screw is intended to stabilize the spine as an aid to fusion through bilateral immobilization of the facet joints. The screws are inserted posteriorly through the superior side of the facet, across the facet joint, and into the pedicle. The PMT Facet Screw is indicated for bilateral facet fixation, with or without bone graft, at single or multiple levels, from C2 to S1. The PMT Facet Screw is indicated for treatment of any or all of the following:

1. Pseudoarthrosis and failed previous fusion
2. Spondylolisthesis
3. Spondylolysis

4. Degenerative disc disease (DDD) as defined by neck and/or back pain of discogenic origin as confirmed by radiographic studies
5. Degeneration of the facets with instability; and
6. Fracture

The PMT Facet Screw is intended for conventional or tissue-sparing surgical placement.

Technological Characteristics:

The PMT Facet Screw is available in fully threaded configurations with diameters of 3.5 mm, 3.75 mm and 4.0 mm and lengths of 13 mm to 25 mm (in 2 mm increments). The PMT Facet Screw is constructed of Titanium-6 Aluminum- 4 Vanadium ELI alloy (conforming to ASTM F136-13) and supplied sterile for single use only.

Performance Testing

The following testing was performed using the subject device:

Static and Dynamic Cantilever Bending

- ASTM F2193-14 Standard Specifications and Test Methods for Components Used in the Surgical Fixation of the Spinal Skeletal System

Static Torsion Testing

- ASTM F543-17 Standard Specification and Test Methods for Metallic Medical Bone Screws

Static Pull-Out Testing

- ASTM F543-17 Standard Specification and Test Methods for Metallic Medical Bone Screws

Drive Torque

- ASTM F543-17 Standard Specification and Test Methods for Metallic Medical Bone Screws

In addition, the following testing was performed:

Pyrogenicity Testing

- Pyrogenicity Testing was conducted in compliance with the FDA Guidance Documents listed below:
  - "Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile: Guidance for Industry and Food and Drug Administration Staff"

- "Pyrogen and Endotoxins Testing: Questions and Answers"

In all instances, the PMT Facet Screw functioned as intended and met all pre-determined acceptance criteria and do not raise new issues of safety or effectiveness; thus demonstrating that the PMT Screw is substantially equivalent to the legally marketed predicate device.

No clinical testing was deemed necessary to support substantial equivalence.

Substantial Equivalence

The PMT Facet Screw has the same indication for use, technological characteristics, and principles of operation as the predicate device. The successful completion of the performance testing further supports the subject PMT Facet Screw's substantial equivalence to the predicate device. No issues of safety or effectiveness are raised by the PMT Facet Screw.