DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 20, 2017

Providence Medical Technology, Inc.
Mr. Edward Liou
Chief Operating Officer
1331 North California Boulevard, Suite 320
Walnut Creek, California 94596

Re: K172279
Trade/Device Name: PMT Posterior Fixation System
Regulatory Class: Unclassified
Product Code: NKG
Dated: July 26, 2017
Received: July 28, 2017

Dear Mr. Liou:

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 (DICE) 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 (DICE) 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,

Ronald P. Jean -S for

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172279

Device Name
PMT Posterior Fixation System

Indications for Use *(Describe)*
The PMT Posterior Fixation System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the cervical spine (C1 to C7) and the thoracic spine from T1 to T3: traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g., pseudarthrosis); tumors involving the cervical spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability.

The PMT Posterior Fixation System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

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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Section 6. 510(k) Summary

510(k) Owner:	Providence Medical Technology, Inc. 1311 N. California Blvd, Suite 320 Walnut Creek, CA 94596 T: 415-923-9376 F: 415-923-9377
Contact Person:	Edward Liou Email: ed@providencemt.com T: 415-923-9376
Date Summary Prepared:	September 19, 2017
Trade Name:	PMT Posterior Fixation System
Common Name:	Orthosis, Cervical Pedicle Screw Spine Fixation
Device Classification Regulation:	Unclassified
Device Product Code & Panel:	NKG Orthopaedic and Rehabilitation Devices Panel
Primary Predicate Device:	Zimmer Spine, Inc. Virage OCT Spinal Fixation System (K151031)

Device Information

A. Device Description

The PMT Posterior Fixation System is a bone screw and rod construct that will be supplied sterile and single use only. It consists of polyaxial screws, fixation rods, and locking set screws. The polyaxial screws are designed to be utilized for pedicle fixation or anchored to the posterior lateral mass of the cervical (C1 to C7) and thoracic (T1 to T3) vertebra. A set screw is used to connect and anchor the rod to each screw head while locking the orientation of the polyaxial screw.

The PMT Posterior Fixation System is manufactured from 6Al-4V Titanium Alloy, conforming to ASTM F136. The polyaxial screw, available in diameters of 3.5mm and 4.0mm, is self-tapping with a range of screw lengths between 8mm to 24mm. The rod is offered in two diameters, 3.5mm and 3.8mm, with a range in lengths of 15mm to 240mm. The screw head that is assembled to the polyaxial screw accepts the 3.5mm or 3.8mm rod. The set screw comes in one size and has a matching thread profile to the screw head.

B. Intended Use and Indications for Use

The PMT Posterior Fixation System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the cervical spine (C1 to C7) and the thoracic spine from T1 to T3: traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g., pseudarthrosis); tumors involving the cervical spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability.

The PMT Posterior Fixation System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

C. Summary of Technological Characteristics

The fundamental operational principles, surgical approach, design, materials, and performance of the PMT Posterior Fixation System and the predicate device are essentially the same. Therefore, the technological characteristics of the PMT Posterior Fixation System do not raise any new or different safety and effectiveness questions not addressed in the predicate device.

D. Summary of Performance Testing

Non-clinical testing conducted per ASTM F1717 (static compression bending, static torsion, and dynamic compression bending) has demonstrated that the PMT Posterior Fixation System is substantially equivalent to the predicate device.

E. Basis of Substantial Equivalence

The PMT Posterior Fixation System is substantially equivalent compared to the cleared predicate device, Virage OCT Spinal Fixation System (K151031), on the basis the devices have the same intended use and indications for use, same technological characteristics, similar design features, and same materials and principles of operation. Performance data demonstrate that the PMT Posterior Fixation System is as safe and effective as the predicate device.