June 25, 2024

Providence Medical Technology, Inc.
% Roxanne Dubois
Regulatory Consultant
R. Dubois Consulting
1399 Robnick Ct.
Campbell, California 95008

Re: K241035
Trade/Device Name: PMT Posterior Cervical Stabilization System (PCSS)
Regulatory Class: Unclassified
Product Code: MRW
Dated: April 15, 2024
Received: April 16, 2024

Dear Roxanne Dubois:

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,

Colin O'neill -S

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K241035

Device Name
PMT Posterior Cervical Stabilization System (PCSS)

Indications for Use *(Describe)*

PMT PCSS is posterior spinal instrumentation with integrated screw fixation intended to provide immobilization and stabilization of spinal segments.

PMT PCSS is placed through a posterior surgical approach in up to 3 consecutive levels of the cervical spine (C3-C7) and achieves bilateral facet fixation by spanning the facet interspace at each level with points of fixation at each end of the construct.

PMT PCSS is intended as an adjunct to posterior cervical fusion (PCF), and is only intended to be used in combination with an anterior cervical discectomy and fusion (ACDF) at the same level(s).

PMT PCSS is indicated for skeletally mature patients with degenerative disc disease (DDD). DDD is defined as radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies. PMT PCSS is to be used with autogenous bone and/or allogenic bone graft.

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.

PROVIDENCE
MEDICAL TECHNOLOGY

Premarket Notification 510(k) Summary

510(k) Owner: Providence Medical Technology, Inc.
4234 Hacienda Dr., Suite 150, Pleasanton, CA 94588
T: 415-923-9376; F: 415-923-9377

Company Contact Person: Edward Liou, ed@providencemt.com; T: 415-754-8593
Submission Correspondent: Roxanne Dubois, rduboisconsulting@gmail.com; T: 408-828-5019

Date Summary Prepared: June 18, 2024

Trade Name: PMT Posterior Cervical Stabilization System (PCSS)

Common Name: Facet Fixation System

Classification & Regulation: Unclassified

Product Code & Panel: MRW; Division of Spinal Devices, Division of Health Technology 6B (DHT6B); Orthopaedic and Rehabilitation Devices Panel

Primary Predicate Device: PMT Facet Fixation System ("PMT FFS"), K220951, Code MRW

A. Device Description

PMT PCSS is posterior spinal instrumentation with integrated screw fixation intended to provide immobilization and stabilization of spinal segments. The device is placed through a posterior surgical approach in up to 3 consecutive levels of the cervical spine (C3-C7) and achieves bilateral facet fixation by spanning the facet interspace at each level with points of fixation at each end of the construct.

The device is manufactured from medical grade titanium alloy (6Al4V) and supplied sterile for single use only with a pre-attached disposable delivery instruments. The implant is fenestrated and is to be used with autogenous bone and/or allogenic bone graft. The design incorporates "windows" through the implant to permit visualization of the graft material and, over time, formation of new bone.

CORUS® Spinal System is used to access and prepare the site for posterior fusion.

B. Indications for Use

PMT Posterior Cervical Stabilization System (PCSS) is posterior spinal instrumentation with integrated screw fixation intended to provide immobilization and stabilization of spinal segments.

PMT PCSS is placed through a posterior surgical approach in up to 3 consecutive levels of the cervical spine (C3-C7) and achieves bilateral facet fixation by spanning the facet interspace at each level with points of fixation at each end of the construct.

PROVIDENCE MEDICAL TECHNOLOGY

PMT PCSS is intended as an adjunct to posterior cervical fusion (PCF) and is only intended to be used in combination with an anterior cervical discectomy and fusion (ACDF) at the same level(s).

PMT PCSS is indicated for skeletally mature patients with degenerative disc disease (DDD). DDD is defined as radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies.

PMT PCSS is to be used with autogenous bone and/or allogenic bone graft.

C. Technological Characteristics

PMT PCSS components are supplied in a variety of sizes to accommodate patient anatomy. The superior and inferior surfaces on the stabilizer feature teeth that provide bony contact with the endplates, a box shape in the center has fenestrations (windows) intended to house bone graft. The integrated screws provide additional anchoring, and delivery instruments facilitate insertion into the facet joint space and feature a physical stop to prevent over-insertion.

D. Performance Testing

No new mechanical bench testing was supplied in this submission given that the subject implants have been previously cleared for the same intended use in K220951.

Non-Clinical performance data included magnetic resonance imaging (MRI) compatibility testing to provide labeling recommendations for 1.5 T and 3 T clinical scanners, including RF Heating Testing per ASTM F2182, Displacement Force and Torque Testing per ASTM F2052, and Image Artifact Testing per ASTM F2119. The results indicated that the devices should be labeled MR Conditional per relevant ASTM standards.

Clinical performance data from a prospective, multicenter, randomized, clinical trial of PCSS was presented. Over 200 subjects with cervical degenerative disc disease at 3 consecutive levels were randomized and treated with either 3-level circumferential cervical fusion with PCSS and ACDF (CCF) (investigational arm) or 3-level ACDF alone (control arm). Radiographic evaluations, peri-operative findings, patient reported outcomes, and other assessments of safety and effectiveness at 12 and 24 months were utilized. At 12 months, the primary endpoint of fusion success demonstrated a superior fusion rate for subjects treated with PCSS and ACDF (CCF) compared to ACDF alone.

These non-clinical and clinical performance data demonstrate the substantial equivalence of safety and effectiveness profiles of PCSS for immobilization and stabilization of the facet joints as an adjunct to tissue-sparing posterior fusion until fusion occurs.

E. Basis of Substantial Equivalence

A comparison of the subject and predicate devices results in a determination of substantial equivalence. The subject and predicate devices have the same intended use, similar indications for use, and same technological characteristics, materials of construction, principles of operation, design features and characteristics.

The conclusions drawn from the performance testing demonstrate that the subject device is as safe, as effective, and performs as well as or better than the predicate device. It is determined that the subject and predicate devices are substantially equivalent.