August 11, 2023

Providence Medical Technology, Inc
Mr. Edward Liou
Chief Operating Officer
4234 Hacienda Drive, Suite 150
Pleasanton, California 94588

Re: K230297
Trade/Device Name: PMT Expandable Cage (PMT EXP)
Regulatory Class: Unclassified
Product Code: MRW
Dated: July 7, 2023
Received: July 10, 2023

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. 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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230297

Device Name
PMT Expandable Cage (PMT EXP)

Indications for Use *(Describe)*

PMT Expandable Cage (PMT EXP) is an integrated construct comprised of a CAVUX Cage-E and a single ALLY Screw-E.
PMT EXP is placed bilaterally through a posterior surgical approach and spans the facet interspace with points of fixation at each end of the construct.
PMT EXP is intended for temporary stabilization as an adjunct to single level posterior cervical fusion in skeletally mature patients. PMT EXP is only intended for use with a single level anterior cervical fusion at the same spinal level that utilizes FDA cleared/approved spine stabilization hardware for anterior cervical fusion procedures.
PMT EXP is indicated for the treatment of patients with cervical degenerative disc disease (DDD) with radiculopathy from C3-C7.
PMT EXP is indicated for use with autogenous 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Premarket Notification 510(k) Summary

Date:	August 8, 2023
Company:	Providence Medical Technology, Inc. 4234 Hacienda Dr., Suite 150, Pleasanton, CA 94588 T: 415-923-9376; F: 415-923-9377
Sponsor Contact:	Edward Liou, ed@providencemt.com; T: 415-754-8593
Regulatory Contact:	Roxanne Dubois, rduboisconsulting@gmail.com; T: 408-828-5019
Proposed Trade Name:	PMT Expandable Cage (PMT EXP)
Common Name:	Facet Screw System
Regulatory Class:	Unclassified
Product Code:	MRW
Primary Predicate Device:	PMT Facet Fixation Screw (FFS), K220951 (Code MRW)
Additional Predicate:	ALLY Facet Screw, K163374 (Product Code MRW)

Device Description

The PMT Expandable Cage (PMT EXP) is comprised of a CAVUX Cage-E and an ALLY Expansion Screw as an integrated construct, manufactured from medical grade titanium and titanium alloy, and supplied sterile for single use only. The components are provided with a pre-attached disposable delivery handle/inserter. The device achieves facet fixation by spanning the interspace with points of fixation at each end of the construct and provides temporary, bilateral, rigid fixation as an adjunct to fusion.

CORUS® Spinal System is recommended to access the site and perform posterior cervical fusion.

The threads of the Expansion Screw interface with the slot features of the Cage-E to increase the height of the Cage-E and promote strength of the total construct. The profile of the Cage-E provides contact area between the device and adjacent bony surfaces to fixate the segment. The Expansion Screw is made of 6AL 4V ELI Titanium (ASTM F136) and the washer is made of Commercially Pure Titanium Grade 2 (ASTM F67).

Indications for Use

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PMT EXP is placed bilaterally through a posterior surgical approach and spans the facet interspace with points of fixation at each end of the construct.
PMT EXP is intended for temporary stabilization as an adjunct to single level posterior cervical fusion in skeletally mature patients. PMT EXP is only intended for use with a single level anterior cervical fusion at the same spinal level that utilizes FDA cleared/approved spine stabilization hardware for anterior cervical fusion procedures.
PMT EXP is indicated for the treatment of patients with cervical degenerative disc disease (DDD) with radiculopathy from C3-C7.
PMT EXP is indicated for use with autogenous and/or allogenic bone graft.

Comparison of Technological Characteristics

The intended use, materials of construction, quality controls, and sterilization methods of the Subject Device are substantially equivalent to the predicate device.

Performance Data

The following mechanical tests were performed on the subject device: static and dynamic axial compression using a custom test setup; and axial pullout testing per ASTM F543. Biomechanical cadaver fatigue and kinematic studies were performed to assess spinal stability provided by the subject device and the risk of device migration.

Clinical data were provided on the subject device comparing to other cervical fusion techniques utilizing radiographic and CT evaluations, peri-operative findings, patient reported outcomes, and assessments of

safety and effectiveness. Clinical and radiographic data provided satisfactory clinical outcomes to support use of the subject device when used at a single level in combination with an anterior cervical fusion procedure and anterior cervical fusion hardware at the same level.

Conclusion

The information submitted by Providence Medical Technology in this premarket notification demonstrates that the subject device performs as intended and is substantially equivalent for its intended use.