December 9, 2022

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

Re: K220951
Trade/Device Name: PMT Facet Fixation System (PMT FFS)
Regulatory Class: Unclassified
Product Code: MRW
Dated: November 7, 2022
Received: November 8, 2022

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)*
K220951

Device Name
PMT Facet Fixation System (PMT FFS)

Indications for Use *(Describe)*

PMT Facet Fixation System (PMT FFS) is an integrated construct comprised of a CAVUX Cage and a single ALLY Bone Screw. PMT FFS is placed bilaterally through a posterior surgical approach and spans the interspace with points of fixation at each end of the construct.
PMT FFS is intended for temporary stabilization as an adjunct to posterior cervical fusion in skeletally mature patients. PMT FFS is indicated for patients requiring a revision for an anterior pseudarthrosis at one level, from C3 to C7, 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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PROVIDENCE MEDICAL TECHNOLOGY

Premarket Notification 510(k) Summary

Date:	December 2, 2022
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 Facet Fixation System (PMT FFS)
Common Name:	Facet Fixation System
Regulatory Class:	Unclassified
Product Code:	MRW
Primary Predicate Device:	PMT Facet Screw cleared under K183589 (code MRW)
Reference Devices:	CAVUX® Cage (K122801) and ALLY® Bone Screw (K170698)

Device Description

The PMT Facet Fixation System (PMT FFS) is composed of CAVUX Cages and ALLY Bone Screws as an integrated construct with both manufactured from medical grade titanium alloy 6Al4V–ELI Ti (ASTM F136) and supplied sterile for single use only. The components are provided with a pre-attached disposable delivery handle/inserter. PMT FFS achieves facet fixation by spanning the interspace with points of fixation at each end of the construct and provides bilateral rigid fixation as an adjunct to fusion with ALLY Bone Screws providing additional anchoring.

CAVUX Cages are fusion devices offered in a variety of sizes to accommodate various patient anatomies and pathology. The center of the cage is hollow and designed to be filled with bone graft into the "windows" to permit formation of new bone through the cage. The ALLY Bone Screw is fully threaded. CORUS® Spinal System is recommended to access the site and perform posterior cervical fusion.

Indications for Use

PMT Facet Fixation System (PMT FFS) is an integrated construct comprised of a CAVUX Cage and a single ALLY Bone Screw. PMT FFS is placed bilaterally through a posterior surgical approach and spans the interspace with points of fixation at each end of the construct. PMT FFS is intended for temporary stabilization as an adjunct to posterior cervical fusion in skeletally mature patients. PMT FFS is indicated for patients requiring a revision for an anterior pseudoarthrosis at one level, from C3 to C7, with autogenous and/or allogenic bone graft.

Comparison of Technological Characteristics

The intended use of the subject PMT FFS is the same as the primary predicate device. The design, materials of construction, sterilization methods of the subject PMT FFS is the same as the reference devices.

Performance Data

The following mechanical tests were performed on the subject PMT FFS: static and dynamic axial compression and compression shear testing per ASTM F2077, screw push-out testing (anti-backout mechanism testing), torsional strength testing per ASTM F543, expulsion testing, and subsidence testing per ASTM F2267.

Clinical data from a prospective multicenter clinical study of the PMT FFS was presented. PMT FFS was compared to other cervical fusion techniques utilizing radiographic and CT evaluations, peri-operative findings, patient reported outcomes, and assessments of safety and effectiveness. Long-term clinical and radiographic data provided satisfactory clinical outcomes.

Conclusion

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