December 19, 2023

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

Re: K230840
Trade/Device Name: PMT Facet Fixation System, Lumbar (PMT FFS-LX)
Regulatory Class: Unclassified
Product Code: MRW
Dated: November 20, 2023
Received: November 21, 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 (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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230840

Device Name
PMT Facet Fixation System , Lumbar (PMT FFS-LX)

Indications for Use *(Describe)*

PMT Facet Fixation System, Lumbar (PMT FFS-LX) is an integrated construct comprised of a CAVUX Cage and an ALLY Bone Screw. PMT FFS-LX is placed bilaterally through a posterior surgical approach and spans the facet interspace with points of fixation at each end of the construct.

PMT FFS-LX is intended to provide temporary stabilization as an adjunct to a 1 or 2 level interbody lumbar fusion with autogenous and/or allogenic bone graft and must be accompanied with an FDA cleared intervertebral body fusion device implanted at the same spinal level(s), and may be used with a pedicle screw and rod system implanted at the same spinal level(s).

PMT FFS-LX is indicated for the treatment of patients with lumbar degenerative disc disease (DDD) from L4 to S1 in skeletally mature patients who have failed conservative care.

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

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:	November 18, 2023
Trade Name:	PMT Facet Fixation System, Lumbar (PMT FFS-LX)
Common Name:	Facet Fixation System
Device Classification Regulation:	Unclassified
Device Product Code & Panel:	MRW; Division of Spinal Devices, Division of Health Technology 6B (DHT6B); Orthopedic and Rehabilitation Devices Panel
Primary Predicate Device:	ALLY Facet Screws (K163374), Product Code MRW, Unclassified
Reference Devices:	PMT Facet Fixation System (FFS) (K220951), Product Code MRW, Unclassified PMT Expandable Cage (PMT EXP) (K230297), Product Code MRW, Unclassified

Device Description

PMT Facet Fixation System, Lumbar (PMT FFS-LX) is composed of CAVUX® Cages and ALLY® Bone Screws, an integrated construct, manufactured from medical grade titanium alloy and supplied sterile for single use only with a pre-attached disposable delivery handle/inserter. PMT FFS-LX provides temporary stabilization by spanning the facet interspace with points of fixation at each end of the construct and provides fixation as an adjunct to fusion. An ALLY Bone Screw is intended to be utilized to provide additional anchoring.

CAVUX Cages are offered in a variety of sizes to accommodate various patient anatomies and pathology. The cage is designed to be filled with bone graft to permit formation of new bone through the device. ALLY Bone Screws are fully threaded. CORUS™ Spinal System is recommended to access the site and perform posterior fusion.

Indications for Use

PMT Facet Fixation System, Lumbar (PMT FFS-LX) is an integrated construct comprised of a CAVUX Cage and an ALLY Bone Screw. PMT FFS-LX is placed bilaerally through a posterior surgical approach and spans the facet interspace with points of fixation at each end of the construct. PMT FFS-LX is intended to provide temporary stabilization as an adjunct to a 1 or 2 level interbody lumbar fusion with autogenous and/or allogenic bone graft and must be accompanied with an FDA cleared intervertebral body fusion device implanted at the same spinal level (s), and may be used with a pedicle screw and rod system implanted at the same spinal level(s).
PMT FFS-LX is indicated for the treatment of patients with lumbar degenerative disc disease (DDD) from L4 to S1 in skeletally mature patients who have failed conservative care.

Comparison of Technological Characteristics

The intended use, materials of construction, and sterilization method is the same as the primary predicate device. The design is the same as the reference devices.

Performance Data

The following mechanical tests were performed on the subject device: 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. An *in-vitro* biomechanical evaluation was also conducted.

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Clinical data were provided on the subject device, comparing to other lumbar 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 as temporary stabilization along with an intervertebral body fusion device at the same spinal level(s) as an adjunct to lumbar fusion.

Conclusion

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