



July 10, 2025

Providence Medical Technology, Inc.
% Roxanne Dubois
Regulatory Consultant
R. Dubois Consulting, LLC
584 Rio Del Mar Blvd.
Aptos, California 95003

Re: K251885

Trade/Device Name: CAVUX Facet Fixation System (CAVUX FFS) and CORUS-LX Implant
Regulatory Class: Unclassified
Product Code: MRW
Dated: June 19, 2025
Received: June 20, 2025

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K251885

?

Please provide the device trade name(s).

?

CAVUX Facet Fixation System (CAVUX FFS);
CORUS-LX Implant

Please provide your Indications for Use below.

?

1. CAVUX Facet Fixation System (CAVUX FFS):

CAVUX Facet Fixation System (CAVUX FFS) is posterior spinal instrumentation with integrated screw fixation intended to provide immobilization and stabilization of spinal segments.

CAVUX FFS is placed bilaterally through a posterior surgical approach and spans the interspace with points of fixation at each end of the construct.

CAVUX FFS is intended for temporary stabilization as an adjunct to posterior cervical fusion in skeletally mature patients.

CAVUX 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.

2. CORUS-LX Implant:

CORUS-LX Implant is posterior spinal instrumentation with integrated screw fixation intended to provide immobilization and stabilization of spinal segments.

CORUS-LX is placed bilaterally through a posterior surgical approach and spans the facet interspace with points of fixation at each end of the construct.

CORUS-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).

CORUS-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.

Please select the types of uses (select one or both, as applicable).

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

?

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 16, 2025

Trade Name: CAVUX Facet Fixation System (CAVUX FFS) and CORUS-LX Implant

Common Name: Facet Fixation System, cervical and lumbar

Device 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: Posterior Cervical Stabilization System (PCSS, K241035)

Additional Predicates: PMT Facet Fixation System (PMT FFS, K220951)
PMT Facet Fixation System, Lumbar (PMT FFS-LX, K230840)

A. Device Description

CAVUX FFS and CORUS-LX Implant are posterior spinal instrumentation with integrated screw fixation intended to provide immobilization and stabilization of spinal segments. CORUS-LX LevelOne is a kit that contains CORUS-LX Implant and accessories.

The devices are placed through a posterior surgical approach and achieve facet fixation by spanning the facet interspace at each level with points of fixation at each end of the construct. The devices are manufactured from medical grade titanium alloy (6Al4V) and supplied sterile for single use only with pre-attached disposable delivery instruments. The implants are fenestrated and 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.

B. Indications for Use**CAVUX Facet Fixation System (CAVUX FFS):**

CAVUX Facet Fixation System (CAVUX FFS) is posterior spinal instrumentation with integrated screw fixation intended to provide immobilization and stabilization of spinal segments.

CAVUX FFS is placed bilaterally through a posterior surgical approach and spans the interspace with points of fixation at each end of the construct.

CAVUX FFS is intended for temporary stabilization as an adjunct to posterior cervical fusion in skeletally mature patients.

CAVUX 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.

CORUS-LX Implant:

CORUS-LX Implant is posterior spinal instrumentation with integrated screw fixation intended to provide immobilization and stabilization of spinal segments.

CORUS-LX is placed bilaterally through a posterior surgical approach and spans the facet interspace with points of fixation at each end of the construct.

CORUS-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).

CORUS-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.

C. Summary of Technological Characteristics

Device 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. Summary of Performance Testing

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

E. Basis of Substantial Equivalence

A comparison of the subject and predicate devices results in a determination of substantial equivalence. The purpose of this submission is to modify the indications for use of the subject devices (originally cleared under K220951 and K230840) to align with language used in a more recent predicate clearance (K241035). The subject and predicate devices have similar indications for use, and the same intended use, technological characteristics, materials of construction, principles of operation, and design features and characteristics.

The conclusions drawn from this regulatory review demonstrate that the subject devices are as safe, as effective, and perform as well as or better than the predicate device. It is determined that the subject and predicate devices are substantially equivalent.