November 20, 2025

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

Re: K253190
Trade/Device Name: CORUS-LX Implant
Regulatory Class: Unclassified
Product Code: MRW
Dated: September 25, 2025
Received: September 26, 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,

EILEEN CADEL -S for

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.	K253190

Please provide the device trade name(s).

CORUS-LX Implant

Please provide your Indications for Use below.

CORUS-LX Implant is posterior spinal instrumentation with integrated screw fixation intended to provide immobilization and stabilization of spinal segments.
CORUS-LX is placed 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 (PSR) implanted at the same spinal level(s) to achieve bilateral posterior stabilization.
The CORUS-LX is intended to be used as part of bilateral posterior fixation that is achieved either with bilateral placement of CORUS-LX Implants or unilateral placement of the CORUS-LX Implant with PSR on the contralateral side.
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)

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:	September 25, 2025
Trade Name:	CORUS-LX Implant
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:	CORUS-LX Implant ("CORUS-LX"), K251885
Additional Predicate:	PMT Facet Fixation System, Lumbar ("PMT FFS-LX"), K230840

A. Device Description

CORUS-LX Implant is 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 (Ti6Al4V) 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.

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

B. Indications for Use

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

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

Premarket Notification 510(k) Summary

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 (PSR) implanted at the same spinal level(s) to achieve bilateral posterior stabilization.

The CORUS-LX is intended to be used as part of bilateral posterior fixation that is achieved either with bilateral placement of CORUS-LX Implants or unilateral placement of the CORUS-LX Implant with PSR on the contralateral side.

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. 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. Performance Testing

No bench or animal performance testing were supplied in this submission given that the subject implants were previously cleared for the same intended use.

Clinical performance data were provided to support the expanded use of the subject device unilaterally with contralateral pedicle screw system placement. Clinical data on subjects implanted with the subject device were provided on a total of 179 cases of which 55 cases (31%) included unilateral implantation of the subject device at one or more levels. No adverse events or subsequent revision surgeries occurred in subjects with unilateral treatment. There were no instances of device loosening, migration, or expulsion in patients implanted with the subject device unilaterally. Similar rates of fusion were observed in patients implanted unilaterally as compared to bilateral cases. The clinical performance data adequately demonstrates substantially equivalent performance of the subject device when implanted unilaterally with contralateral pedicle screw system placement.

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 similar indications for use, and the same intended use, technological characteristics, materials of construction, principles of operation, design features and characteristics. This submission seeks expansion of the indications for use of the subject device to be implanted unilaterally with contralateral pedicle screw system placement.

The conclusions drawn from the clinical performance data and regulatory review demonstrate that the subject device is substantially equivalent to the predicate device.