May 14, 2026

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

Re: K253676
Trade/Device Name: CORUS™ Posterior Cervical Stabilization System 3D (CORUS™ PCSS 3D)
Regulatory Class: Unclassified
Product Code: MRW
Dated: November 20, 2025
Received: November 21, 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K253676

Device Name
CORUS™ Posterior Cervical Stabilization System 3D (CORUS™ PCSS 3D)

Indications for Use *(Describe)*
CORUS™ Posterior Cervical Stabilization System 3D (CORUS™ PCSS 3D) is posterior spinal instrumentation with integrated screw fixation intended to provide immobilization and stabilization of spinal segments.

CORUS PCSS 3D is placed through a posterior surgical approach in up to 3 consecutive levels of the cervical spine (C3-C7) and achieves bilateral facet fixation by spanning the facet interspace at each level with points of fixation at each end of the construct.

CORUS PCSS 3D is intended as an adjunct to posterior cervical fusion (PCF) and is only intended to be used in combination with FDA cleared/approved spine stabilization hardware for anterior cervical fusion at the same level(s).

CORUS PCSS 3D is indicated for skeletally mature patients with degenerative disc disease (DDD). DDD is defined as radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies.

CORUS PCSS 3D is to be used with autogenous bone 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.

Premarket Notification 510(k) Summary

510(k) Owner: Providence Medical Technology, Inc. (Providence)
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: May 13, 2026

Trade Name: CORUS™ Posterior Cervical Stabilization System 3D (CORUS™ PCSS 3D)

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

Predicate Device:
PMT Posterior Cervical Stabilization System (PCSS), K241035

Reference Device:
iFuse Implant System; iFuse-3D Implant, K162733
PMT Expandable Cage (PMT EXP); K230297

A. Device Description

CORUS PCSS 3D is posterior spinal instrumentation with integrated screw fixation intended to provide immobilization and stabilization of spinal segments. The device is placed through a posterior surgical approach in up to 3 consecutive levels of the cervical spine (C3-C7) and achieves bilateral facet fixation by spanning the interspace at each level with points of fixation at each end of the construct.

The device is manufactured from medical grade titanium alloy (6Al4V) and supplied sterile for single use only with pre-attached disposable delivery instruments. The implant is fenestrated with a porous lattice and is designed to be used with autogenous bone and/or allogenic bone graft. The fenestrations through the implant permit visualization of the graft material and, over time, formation of new bone through the implant.

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

B. Indications for Use

CORUS™ Posterior Cervical Stabilization System 3D (CORUS™ PCSS 3D) is posterior spinal instrumentation with integrated screw fixation intended to provide immobilization and stabilization of spinal segments.

CORUS PCSS 3D is placed through a posterior surgical approach in up to 3 consecutive levels of the cervical spine (C3-C7) and achieves bilateral facet fixation by spanning the facet interspace at each level with points of fixation at each end of the construct.

Premarket Notification 510(k) Summary

CORUS PCSS 3D is intended as an adjunct to posterior cervical fusion (PCF) and is only intended to be used in combination with FDA cleared/approved spine stabilization hardware for anterior cervical fusion at the same level(s).

CORUS PCSS 3D is indicated for skeletally mature patients with degenerative disc disease (DDD). DDD is defined as radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies.

CORUS PCSS 3D is to be used with autogenous bone and/or allogenic bone graft.

C. Technological Characteristics

CORUS PCSS 3D 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. The subject of this premarket notification is to allow an alternate additive manufacturing process and minor geometry changes for the Stabilizer 3D component of CORUS PCSS 3D.

D. Performance Testing

The following mechanical bench testing was successfully completed to demonstrate substantial equivalence:

- Subsidence Testing (ASTM F2267)
- Expulsion Testing (ASTM Draft Standard, F-04-25-02-02)
- Custom Static Screw Push-Out Testing
- Static and Dynamic Axial Compression Testing (ASTM F2077)
- Static and Dynamic Compression Shear Testing (ASTM F2077)
- Particulate Analysis of ASTM F2077 Dynamic Axial Compression and Dynamic Compression Shear Runout (ASTM F1877)
- Lattice Characterization (ASTM F1044, ASTM F1147, ASTM F1160, ASTM F1854 and ASTM F1978)
- Magnetic resonance imaging (MRI) compatibility to provide labeling recommendations for 1.5 T and 3 T clinical scanners, including RF Heating (ASTM F2182), Displacement Force and Torque (ASTM F2052), and Image Artifact (ASTM F2119). Data indicated that the devices should be labeled MR Conditional per relevant ASTM standards.

E. Basis of Substantial Equivalence

A comparison of the subject and predicate devices supports a determination of substantial equivalence. The subject and predicate devices have the same intended use, similar indication for use, and substantially the same technological characteristics, materials of construction, principles of operation, design features, and characteristics.

The conclusions drawn from the performance testing demonstrate that the subject device is substantially equivalent to the predicate devices.