October 15, 2021

Providence Medical Technology, Inc.
Edward Liou
Chief Operating Office
4234 Hacienda Dr., Suite 150
Pleasanton, California 94588

Re: K212636
Trade/Device Name: CORUS™ Spinal System-X
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX
Dated: August 16, 2021
Received: August 19, 2021

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,

for

Laura C. Rose, Ph.D.
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma 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)*

K212636

Device Name

CORUS™ Spinal System-X

Indications for Use *(Describe)*

For Cervical Fusion:
CORUS™ Spinal System-X is a set of instruments indicated to be used to perform posterior cervical fusion in patients with cervical degenerative disc disease.

For Lumbar Fusion:
CORUS™ Spinal System-X is a set of instruments indicated to be used to perform posterior lumbar fusion in patients with lumbar degenerative disc disease.

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
Contact Person:	Edward Liou Email: ed@providencemt.com T: 415-754-8593
Date Summary Prepared:	October 14th, 2021
Trade Name:	CORUS™ Spinal System-X
Common Name:	Arthroscopic Accessories
Device Classification Regulation:	21 CFR 888.1100
Device Product Code & Panel:	HRX Orthopaedic and Rehabilitation Devices Panel
Primary Predicate Device:	Providence Medical Technology, Inc. CORUS™ Spinal System (K190201)
Secondary Predicate Device:	Vertos Medical, Inc. Vertos medical mild™ Device Kit (K093062)

Device Information

A. Device Description

The CORUS™ Spinal System-X is a set of instruments indicated for performing posterior cervical or lumbar fusion. The instruments will be supplied sterile and single use only. The system consists of:

- Access Chisel
- Access Chisel Handle
- Trephine Decorticator
- Guide Tube
- Rasp Decorticator
- Rotary Decorticator
- Bone Graft Tamp

- Multi-Tool
- Guide Tube Adapter

These instruments allow the user to access the posterior cervical or lumbar spine to perform posterior fusion by decortication of bone surfaces, including the posterior lateral mass and facet joints, combined with application of autograft or allograft.

B. Indications for Use

For Cervical Fusion:
CORUS™ Spinal System-X is a set of instruments indicated to be used to perform posterior cervical fusion in patients with cervical degenerative disc disease.

For Lumbar Fusion:
CORUS™ Spinal System-X is a set of instruments indicated to be used to perform posterior lumbar fusion in patients with lumbar degenerative disc disease.

C. Summary of Technological Characteristics

The purpose of if this 510(k) is to expend the labeling and introduce minor physical and mechanical changes to Providence Medical Technology's own instrument system. The fundamental operational principles, surgical approach, design, materials, and performance of the CORUS™ Spinal System-X and the predicate device are essentially the same. Therefore, the technological characteristics of the CORUS™ Spinal System-X do not raise any new safety and effectiveness questions not addressed in the predicate device.

D. Summary of Performance Testing

Non-clinical testing has demonstrated that the CORUS™ Spinal System-X is in compliance with the expectations of the medical community and the product labeling, and that it can be used in accordance with the Indications for Use.

- Simulated use cadaveric testing demonstrated the instruments can be used to perform posterior cervical or lumbar fusion in patients with cervical or lumbar degenerative disc disease.
- The bench testing demonstrated the safety and efficacy of the instruments and the strength and integrity to resist impaction, insertion, removal, and rotational loads to perform the stated intend use.
- Shelf life and package performance testing conducted in accordance with ISO 11607-1:2019 *Annex B, Performance testing*, ASTM D4169-16 *Practice for performance testing of shipping containers and systems (DC13)* and ASTM F1980 *Accelerated Aging* demonstrated the safety and reliability of the labeled two-year shelf life of CORUS™ Spinal System-X.
- Additionally, the CORUS™ Spinal System-X demonstrated that it is in compliance with the following FDA consensus standards:

- FDA Recognition Number 14-528: ISO 11137-1:2006(R)2015 Sterilization Of Health Care Products - Radiation - Part 1: Requirements For Development, Validation And Routine Control Of A Sterilization Process For Medical Devices [Including: Amendment 1 (2013) and Amendment 2 (2019)]
- FDA Recognition Number 14-409: ISO 11137-2:2013: Sterilization of Health Care Products – Radiation – Part 2: Establishing the sterilization dose
- FDA Recognition Number 14-514: ISO 11737-1:2018: Sterilization of health care products — Microbiological methods — Part 1: Determination of a population of microorganisms on products
- FDA Recognition Number 14-540: ISO 11737-2:2019: Sterilization of medical devices — Microbiological methods — Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
- FDA Recognition Number 14-530: ISO 11607-1:2019 Packaging for Terminally Sterilized Medical Devices - Part 1: Requirements for Materials, Sterile Barrier Systems And Packaging Systems
- FDA Recognition Number 14-531: ISO 11607-2:2019 Packaging for Terminally Sterilized Medical Devices – Part 2: Validation Requirements for Forming, Sealing and Assembly Processes
- FDA Recognition Number 2-258: ANSI AAMI ISO10993-1:2018 Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing Within A Risk Management Process
- FDA Recognition Number 8-344: ISO 7153-1 Second Edition 1991-04-01 Surgical Instruments -- Metallic Materials -- Part 1: Stainless Steel [Including Amendment 1 (1999)]
- FDA Recognition Number 8-343: ASTM F899-12b Standard Specification for Wrought Stainless Steels for Surgical Instruments

E. Basis of Substantial Equivalence

The CORUS™ Spinal System-X is substantially equivalent compared to the cleared predicate device, Providence Medical Technology, Inc., CORUS™ Spinal System (K190201) and the secondary predicate device Vertos Medical, Inc., Vertos Medical mild® Device Kit (K093062), on the basis the devices have the same technological characteristics, similar design features, same materials, and principles of operation. Performance data demonstrate that the CORUS™ Spinal System-X is as safe and effective as the predicate devices.