May 3, 2024

Providence Medical Technology, Inc.
% Hannah Taggart, MS
Regulatory Associate
Empirical Technologies
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K240625
Trade/Device Name: CORUS™ Navigation Access System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: March 5, 2024
Received: March 6, 2024

Dear Ms. Taggart:

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,

Shumaya Ali -S

Shumaya Ali, M.P.H.
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)*
K240625

Device Name
CORUS™ Navigation Access System

Indications for Use *(Describe)*

The CORUS™ Navigation Access System for use with the CORUS™ Spinal System is intended to be used during spinal surgery to assist the surgeon in locating and preparing facet joints in either open, or minimally invasive procedures. The CORUS™ Navigation Access System is specifically designed for use with the Medtronic StealthStation™ System, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as a long bone, or vertebra can be identified relative to a CT or MR-based model, fluoroscopy images, or digitized landmarks of the anatomy.

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. 4234 Hacienda Dr. Suite 150, Pleasanton, California 94588 T: 415-923-9376; F: 415-923-9377
Company Contact Person:	Edward Liou, Providence Medical Technology, Inc. 415-754-8593; ed@providencemt.com
Submission Correspondent:	Hannah Taggart, MS, Empirical Technologies 719-457-1152; htaggart@empiricaltech.com
Date Summary Prepared:	April 23, 2024
Trade Name:	CORUS™ Navigation Access System
Common Name:	Stereotaxic Instruments
Device Classification Name:	Orthopedic Stereotaxic Instruments
Classification & Regulation:	Class II per 21 CFR §882.4560
Product Code:	OLO
Panel:	Orthopedic – Stereotaxic, Trauma, and Restorative Devices (DHT6C)

DEVICE DESCRIPTION:

The CORUS™ Navigation Access System is a manually operated disposable instrument set to be used with the Medtronic StealthStation™ System to assist the surgeon in precise site preparation during open or minimally invasive spinal surgery. The CORUS™ Navigation Access System includes the Navigated Access Chisel, Guide Tube, and Trephine Decorticator. The instruments are manufactured from stainless steel.

INDICATIONS FOR USE

The CORUS™ Navigation Access System for use with the CORUS™ Spinal System is intended to be used during spinal surgery to assist the surgeon in locating and preparing facet joints in either open, or minimally invasive procedures. The CORUS™ Navigation Access System is specifically designed for use with the Medtronic StealthStation™ System, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as a long bone, or vertebra can be identified relative to a CT or MR-based model, fluoroscopy images, or digitized landmarks of the anatomy.

TECHNOLOGICAL CHARACTERISTICS

The subject has similar indications for use, materials, sterilization method, technological characteristics, geometry, and compatibilities with Medtronic StealthStation™ System as the predicates devices and the minor differences do not raise any new issues of safety and effectiveness.

Predicate Devices

510k #	Trade Name	Manufacturer	Product Code	Predicate Type
K211441	Navigated Anterolateral Disc Prep Instruments	Medtronic Sofamor Danek USA, Inc.	OLO	Primary
K212636	CORUS™ Spinal System-X	Providence Medical Technology	HRX	Additional
K150231	Navigated Disc Preparation Instruments	Medtronic Sofamor Danek, USA Inc.	OLO	Additional

PERFORMANCE DATA

The CORUS™ Navigation Access System has been evaluated though an engineering analysis and geometric comparison to the predicate device. A validation was also conducted to demonstrate navigation compatibility with the Medtronic StealthStation™ System. The results show that the subject device is substantially equivalent to the cleared predicates.

CONCLUSION

The overall technological characteristics, engineering analysis, geometric comparison, and navigation compatibility validation lead to the conclusion that the CORUS™ Navigation Access System is substantially equivalent to the predicate device.