



July 30, 2025

Providence Medical Technology, Inc.
% Hannah Taggart
Engineer & Regulatory Specialist
Empirical Technology
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K251060

Trade/Device Name: CORUS™ Navigation System-GX
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: July 1, 2025
Received: July 1, 2025

Dear Hannah 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.

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,

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

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.

K251060

?

Please provide the device trade name(s).

?

CORUS™ Navigation System-GX

Please provide your Indications for Use below.

?

The CORUS™ Navigation System-GX 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 System-GX is specifically designed for use with the Globus Medical ExcelsiusGPS™ which is intended for use as an aid for precisely locating anatomical structures and for the spatial positioning and orientation of an instrument holder or guide tube to be used by surgeons for navigating and/or guiding compatible surgical instruments in open or percutaneous procedures provided that the required fiducial markers and rigid patient anatomy can be identified on CT scans or fluoroscopy.

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)

?

K251060 510(K) SUMMARY

510(k) Owner:	Providence Medical Technology, Inc. 4234 Hacienda Drive, Suite 150 Pleasanton CA, 94588	
Company Contact Person:	Edward Liou; Providence Medical Technology, Inc. 415-754-8593; ed@providencemt.com	
Contact Person:	Hannah Taggart, MS; Empirical Technologies 719- 457-1152; htaggart@empiricaltech.com	
Date Summary was Prepared:	July 29, 2025	
Trade or Proprietary Name:	CORUS™ Navigation System-GX	
Device Classification Name:	Orthopedic Stereotaxis Instruments	
Classification & Regulation #:	Class II per 21 CFR §882.4560	
Product Code:	OLO	
Classification Panel:	Orthopedic – Restorative, Repair and Trauma Devices (DHT6C)	

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The CORUS™ Navigation System-GX disposable instruments are used during the preparation and usage of CORUS™ Spinal System during spinal surgery to assist the surgeon in locating anatomical structures, such as the facet joint, in either open or minimally invasive procedures. The Navigation Access Chisel-G and Navigation Chisel Rasp-G are specifically designed for use with Globus Medical ExcelsiusGPS™ for navigation of the instruments to the facet joint. The instrument set provides access to the posterior spinal facet joint and decortication for bone preparation.

INDICATIONS FOR USE

The CORUS™ Navigation System-GX 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 System-GX is specifically designed for use with the Globus Medical ExcelsiusGPS™ which is intended for use as an aid for precisely locating anatomical structures and for the spatial positioning and orientation of an instrument holder or guide tube to be used by surgeons for navigating and/or guiding compatible surgical instruments in open or percutaneous procedures provided that the required fiducial markers and rigid patient anatomy can be identified on CT scans or fluoroscopy.

TECHNOLOGICAL CHARACTERISTICS

The predicates included in this submission were selected based on the best practices described in the FDA Draft Guidance document *Best Practices for Selecting a Predicate Device to Support a Premarket Notification [510(k)] Submission*. The subject and predicate devices have nearly identical technological characteristics and the minor differences do not raise any new issues of safety and effectiveness. Specifically, the following characteristics are the same between the subject and predicates:

- Indications for Use
- Materials of manufacture
- Critical Geometry
- Principles of Operation

Predicate Devices

510k #	Trade or Proprietary or Model Name	Manufacturer	Product Code	Predicate Type
K191100	ExcelsiusGPS Spine 1.1 Interbody Module	Globus Medical Inc.	OLO	Primary
K212636	CORUS Spinal System-X	Providence Medical Technologies, Inc.	HRX	Additional
K240625	CORUS™ Navigation Access System	Providence Medical Technologies, Inc.	OLO	Additional

The Globus ExcelsiusGPS system includes the navigation platform software and hardware while the subject instruments are used in conjunction with the predicate navigation platform software and hardware the same as the predicate instrument in place of the Globus instruments. The subject does not include its own navigation platform.

PERFORMANCE DATA

The CORUS™ Navigation System-GX instruments have been evaluated through an engineering analysis and geometric comparison to predicate devices to establish the safety and efficacy for accuracy performance. A functional assessment was conducted to evaluate compatibility and simulated use testing. The biocompatibility evaluation of the instruments leveraged equivalence in materials and manufacturing to previously cleared instruments (K180876). The results of these engineering analysis and evaluations show that the subject is substantially equivalent to the cleared predicate.

CONCLUSION

The overall technology characteristics and mechanical performance data lead to the conclusion that the CORUS™ Navigation System-GX is substantially equivalent to the predicate device.