June 18, 2026

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

Re: K261665
Trade/Device Name: CORUS™ Navigation System-GN
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: May 20, 2026
Received: May 20, 2026

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 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,

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.	K261665

Please provide the device trade name(s).

CORUS™ Navigation System-GN

Please provide your Indications for Use below.

The CORUS™ Navigation System-GN 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-GN 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 (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(K) SUMMARY

Submitter's Name:	Providence Medical Technology, Inc.
Submitter's Address:	4234 Hacienda Drive, Suite 150 Pleasanton CA, 94588
Company Contact:	Edward Liou; Providence Medical Technology, Inc. 415-754-8593; ed@providencemt.com
Contact Person:	Hannah Taggart, MS, RAC ATS Colorado Springs 719- 457-1152 htaggart@atslab.com
Date Summary was Prepared:	May 19, 2026
Trade or Proprietary Name:	CORUS™ Navigation System-GN
Device Classification Name:	Orthopedic Stereotaxic 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-GN single use sterile instruments are used during the preparation 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-GN and Navigation Rasp Decorticator-GN 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.

The purpose of this Special 510(k) is to add additional navigation instruments which are compatible with an updated version of the Globus ExcelsiusGPS™ software and associated tracking arrays.

INDICATIONS FOR USE

The CORUS™ Navigation System-GN 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-GN 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 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 Number	Trade or Proprietary or Model Name	Manufacturer	Product Code	Predicate Type
K191100	ExcelsiusGPS® Spine 1.1 Interbody Module	Globus Medical Inc.	OLO	Primary
K251060	CORUS™ Navigation System-GX	Providence Medical Inc.	OLO	Reference

The Globus ExcelsiusGPS system includes the navigation platform software and hardware while the subject instruments are used in in place of the Globus instruments. The subject does not include its own navigation platform. There are no differences between the subject and predicate devices which raise questions for the safety and efficacy of the subject devices.

PERFORMANCE DATA

The CORUS™ Navigation System-GN instruments have been evaluated through an engineering analysis and geometric comparison to predicate devices and a registration validation to establish substantial equivalence. The results of this engineering analysis show that the subject instruments are substantially equivalent to the cleared predicate. The results of the registration validation show that the subject instruments are compatible with the software.

The results of this non-clinical testing show that the CORUS™ Navigation System-GN is sufficient for its intended use and is substantially equivalent to legally marketed predicate devices.

CONCLUSION

The overall technological characteristics and performance lead to the conclusion that the CORUS™ Navigation System-GN is substantially equivalent to the predicate device.