November 5, 2025

Globus Medical, Inc.
Jennifer Antonacci
Director, Regulatory Affairs
Valley Forge Business Center
2560 General Armistead Ave
Audubon, California 19403

Re: K250599
Trade/Device Name: ExcelsiusGPS™ Instruments
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: September 5, 2025
Received: September 8, 2025

Dear Jennifer Antonacci:

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.	K250599

Please provide the device trade name(s).

ExcelsiusGPS Instruments

Please provide your Indications for Use below.

ExcelsiusGPS™
ExcelsiusGPS™ 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. The system is indicated for the placement of spinal and orthopedic bone screws and interbody fusion devices.

ExcelsiusHub™
ExcelsiusHub™ is intended for use as an aid for precisely locating anatomical structures to be used by surgeons for navigating 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. The system is indicated for the placement of spinal and orthopedic bone screws and interbody fusion devices.

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)

510(k) Summary: ExcelsiusGPS™ Instruments

Company: Globus Medical Inc.
2560 General Armistead Ave.
Audubon, PA 19403
610-930-1800

Primary Contact: Jennifer Antonacci, Ph.D.
Director, Regulatory Affairs

Date Prepared: February 28, 2025

Device Name: ExcelsiusGPS™ Instruments

Common Name: Navigated instruments

Classification: Per 21 CFR as follows:
§882.4560 Stereotaxic instrument
Product Code(s): OLO
Regulatory Class: II

Primary Predicate: ExcelsiusGPS™ Spine 1.1 Interbody Module (K191100)

Additional Predicates:
ExcelsiusHub™ (K211616)
HEDRON™ & SABLE™ Spacers (K222270)
NuVasive™ Modulus™ XLIF Interbody System (K201692, K203714)
NuVasive™ Cohere™ XLIF Thoracolumbar Interbody System (K200953, K203714)
NuVasive™ Modulus™ TLIF-O (K172341, K203714)
NuVasive™ Cohere™ TLIF-O (K193541, K203714)
ELSA™ Spacers (K161379, K203278)

Purpose:
The purpose of this submission is to request clearance of additional ExcelsiusGPS™ instruments for use with additional interbody fusion devices in conjunction with ExcelsiusGPS™ or ExcelsiusHub™.

Device Description:
Subject ExcelsiusGPS™ instruments consist of verification adapters and surgical instruments, including interbody inserters and trials, that may be used manually or navigated with the use of ExcelsiusGPS™ or ExcelsiusHub™. The surgical instruments are used to prepare the implant site or implant the device. Instruments are non-sterile and reusable.

Indications for Use:
ExcelsiusGPS™ 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. The system is indicated for the placement of spinal and orthopedic bone screws and interbody fusion devices.

ExcelsiusHub™ is intended for use as an aid for precisely locating anatomical structures to be used by surgeons for navigating 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. The system is indicated for the placement of spinal and orthopedic bone screws and interbody fusion devices.

Technological Characteristics:
The subject ExcelsiusGPS™ instruments have the same or similar technological characteristics as the predicate instruments including design, intended use, material composition, function, and range of sizes. The subject instruments differ in the tip geometries and dimensions in order to accommodate the interbody devices the instruments are used with. These differences are minor and do not raise any new concerns of safety or effectiveness for the subject instruments.

Performance Testing:
Verification, including instrument integration, and comparison to the predicate devices confirm that the ExcelsiusGPS™ instruments meet performance requirements and demonstrate that the subject instruments can be used in accordance with the indications for use. Biocompatibility of patient-contacting materials was demonstrated by using the same materials that are used for the predicate devices.

Basis of Substantial Equivalence:
The ExcelsiusGPS™ instruments have been found to be substantially equivalent to the predicate devices with respect to technical characteristics, performance, and intended use. The information provided within this premarket notification supports substantial equivalence of the subject device to the predicate devices.