Globus Medical Inc.
Kelly Baker
Senior Vice President, Regulatory and Clinical Affairs
2560 General Armistead Ave.
Audubon, Pennsylvania 19403

July 24, 2019

Re: K191100
Trade/Device Name: ExcelsiusGPS Spine 1.1 Interbody Module
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: April 24, 2019
Received: April 25, 2019

Dear Kelly Baker:

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, Shumaya Ali, MPH
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K191100

Device Name

ExcelsiusGPS® Spine 1.1 Interbody Module

Indications for Use *(Describe)*

The 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.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K191100

510(k) Summary: ExcelsiusGPS® Spine 1.1 Interbody Module

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

Contact: Kelly J. Baker, Ph.D.
Senior Vice President, Regulatory and Clinical Affairs

Date Prepared: April 24, 2019

Device Name: ExcelsiusGPS® Spine 1.1 Interbody Module

Common Name: Computer-assisted surgical device

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

Primary Predicate: ExcelsiusGPS® (K171651)
Other Predicates: Medtronic StealthStation S8 (K170011)
Medtronic Navigated Elevate Inserter & Disc Prep (K163581)
SUSTAIN® Lumbar (K130478)
CALIBER® (K102293)
RISE® (K113447)
ALTERA® (K140411)
ELSA® (K161379)

Purpose:
The purpose of this submission is to request clearance of the ExcelsiusGPS® Spine 1.1 Interbody Module software and navigated instruments for access, preparation and placement of lumbar interbody fusion devices (lateral or posterior approaches).

Device Description:
The ExcelsiusGPS® Interbody Module includes hardware and software that enables real time surgical navigation using radiological patient images (preoperative CT, intraoperative CT and fluoroscopy), using a dynamic reference base and positioning camera. The navigation system determines the registration or mapping between the virtual patient (points on the patient images) and the physical patient (corresponding points on the patient's anatomy). Once this registration is created, the software displays the relative position of a tracked instrument, on the patient images. As an aid to visualization, the surgeon can plan implant placement on the patient images prior to surgery. Registration provides the

necessary information to provide visual assistance to the surgeon during freehand navigation. During surgery, the system tracks the position of GPS compatible instruments in or on the patient anatomy and continuously updates the instrument position on patient images utilizing optical tracking. System software is responsible for all navigation functions, data storage, network connectivity, user management, case management, and safety functions. ExcelsiusGPS® surgical instruments are non-sterile, re-usable instruments that are operated manually.

ExcelsiusGPS® Interbody Module instruments include registration instruments, patient reference instruments, and surgical instruments. Registration instruments incorporate arrays of reflective markers, and are used to track patient anatomy and surgical instruments and implants; components include the verification adapters, surveillance marker, surgical instrument arrays, intra-op CT registration fixture, fluoroscopy registration fixture, and dynamic reference bases (DRB and DRB2). Patient reference instruments are either clamped or driven into any appropriate rigid anatomy that is considered safe and provides a point of rigid fixation for the DRBs. Surgical instruments are used to prepare the implant site or implant the device, and include instrument handles, disc prep and trial instruments, interbody inserters, and a dilator holder. The Motion Lock End Effector attaches to the robotic arm and provides a rigid attachment connection for a surgical retractor or port.

Indications for Use:
The 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.

Technological Characteristics:
The ExcelsiusGPS® Interbody Module and associated instruments have similar technological characteristics to the predicate devices including the main system components, workflow, user interface, software features, and design. The ExcelsiusGPS® Interbody Module is comparable to the predicates in terms of intended use, fundamental scientific technology, technological characteristics and principle of operation. Instruments for access, disc preparation, trialing, and interbody placement are modified to facilitate navigation.

Performance Testing:
Verification and validation testing was conducted on ExcelsiusGPS® Interbody Module to confirm that the device meets performance requirements under the indications for use and to ensure safety and efficacy of the system:

- Non-clinical system, software, and instrument verification and validation - Demonstrated compliance with user needs and corresponding design inputs

- Surgical simulations conducted on phantom models - Sawbone models and registration matrix were used to quantify accuracy in a controlled setting
- Human cadaveric quantitative validation under clinically relevant scenarios - Demonstrated system accuracy in navigating interbody fusion devices to the desired location on patient images
- Usability testing user feedback - Collected comments from users and summarized for potential improvements on items for future release considerations.

Biocompatibility:
The biocompatibility evaluation for ExcelsiusGPS® has been conducted in accordance with ISO 10993 standards and blue book memorandum #G95-1 entitled "Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part-1: Evaluation and Testing", May 1, 1995 and FDA Guidance "Biological Evaluation of Medical Devices – Part 1: Evaluation and testing within a risk management process," June 16, 2016. The evaluation confirms that ExcelsiusGPS® meets biocompatibility requirements.

Software Verification and Validation Testing:
Software validation and verification testing was performed in accordance with the FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 11, 2005). The software for this device is considered a "MAJOR" level of concern.

Basis of Substantial Equivalence:
ExcelsiusGPS® Interbody Module has 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 to the predicate devices.