July 10, 2020

Globus Medical Inc.
Jennifer Antonacci
Group Manager, Regulatory Affairs
2560 General Armistead Ave.
Audubon, Pennsylvania 19403

Re: K200047
Trade/Device Name: ExcelsiusGPS Cranial 1.0 Module
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO, HAW
Dated: June 11, 2020
Received: June 12, 2020

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 (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,

Adam D. Pierce, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine 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)*
K200047

Device Name
ExcelsiusGPS Cranial 1.0 Module

Indications for Use *(Describe)*
The ExcelsiusGPS is intended for use as an aid for precisely locating anatomical structures and for 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 spacers, and intracranial devices including biopsy needles, electrodes, and tubes.

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.

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510(k) Summary: ExcelsiusGPS Cranial 1.0 Module

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

Primary Contact: Jennifer Antonacci, Ph.D.
Group Manager, Regulatory Affairs

Date Prepared: July 10, 2020

Device Name: ExcelsiusGPS® Cranial 1.0 Module

Common Name: Computer-assisted surgical device

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

Primary Predicate: ExcelsiusGPS® (K171651)

Other Predicates: ExcelsiusGPS® Spine 1.1 Interbody Module (K191100)
Medtronic StealthStation S8 (K162309)
ROSA ONE Brain (K182417)

Purpose:
The purpose of this submission is to request clearance of the ExcelsiusGPS® Cranial 1.0 Module software and navigated instruments for access, preparation, and placement of cranial devices.

Device Description:
The ExcelsiusGPS® Cranial Module includes hardware and software that enables real time surgical navigation using radiological patient images (MRI, 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 trajectories for instrument 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 include non-sterile, re-usable instruments and sterile instruments that are operated manually or with the use of the positioning system.

The ExcelsiusGPS® Cranial Module is designed to assist with stereotactic procedures that include guidance to cranial targets for instrument navigation and device placement. Instruments consist of end effector instruments, registration instruments, navigated instruments, patient positioning instruments, and surgical instruments. End effector instruments include instruments to connect to the Interchangeable Guide End Effector. Registration and navigated instruments incorporate unique array patterns with reflective markers, and are used to track patient anatomy and surgical instruments. Patient positioning instruments aid in patient fixation. Surgical instruments are used to access and prepare the local site and place devices, such as needles, electrodes, and tubes. The ExcelsiusGPS® Cranial Module is suitable for use in adult and pediatric patient populations in which the use of stereotactic neurosurgery may be appropriate.

Indications for Use:
The ExcelsiusGPS® is intended for use as an aid for precisely locating anatomical structures and for 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 spacers, and intracranial devices including biopsy needles, electrodes, and tubes.

Technological Characteristics:
The ExcelsiusGPS® Cranial 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® Cranial Module is comparable to the predicates in terms of intended use, fundamental scientific technology, technological characteristics and principle of operation.

Comparison of Principles of Operation and Technological Characteristics

Device	Subject ExcelsiusGPS® Cranial Module	Predicate ExcelsiusGPS® (K171651, K191100)	Predicate StealthStation S8 (K162309)	Predicate ROSA ONE Spine (K182417)
Principle of operation	- Intraoperative/ preoperative images - Patient registration - Surgical planning - Real-time tracking of navigated instruments	- Intraoperative/ preoperative images - Patient registration - Surgical planning - Real-time tracking of navigated instruments	- Intraoperative/ preoperative images - Patient registration - Surgical planning	- Intraoperative/ preoperative images - Patient registration - Surgical planning - Guidance of instruments

Device	Subject ExcelsiusGPS® Cranial Module	Predicate ExcelsiusGPS® (K171651, K191100)	Predicate StealthStation S8 (K162309)	Predicate ROSA ONE Spine (K182417)
	- Guidance of instruments	- Guidance of instruments	- Real-time tracking of navigated instruments	
Input images	3D preoperative exam 3D intraoperative exam 2D intraoperative exam	3D preoperative exam 3D intraoperative exam 2D intraoperative exam	3D preoperative exam 3D intraoperative exam 2D intraoperative exam	3D preoperative exam 3D intraoperative exam 2D intraoperative exam
Integrated planning software	ExcelsiusGPS® Planning and Navigation Application Software	ExcelsiusGPS® Planning and Navigation Application Software	Stealthstation Cranial	ROSANNA BRAIN
Save/load planning	Yes	Yes	Yes	Yes
Merge images functionality	Yes	Yes	Yes	Yes
Image-guided	Yes	Yes	Yes	Yes
Patient registration method	Intra-Op CT: Registration Fixture Fluoroscopy: Registration Fixture Stereotactic Localizer Registration	Intra-Op CT: Registration Fixture Pre-Op CT: Fluoroscopic to Pre-Op CT Merge Fluoroscopy: Registration Fixture	Point-to-point registration with anatomical markers or skin/bone fiducials Optical or electromagnetic trace merge Intra-Op CT: Calibrated CT gantry to camera merge Stereotactic Localizer Registration	Point-to-point registration with anatomical markers or skin/bone fiducials Stereotactic Localizer Registration Optical surface registration
Accuracy verification on anatomical landmarks	Yes	Yes	Yes	Yes
Real time display of instrument position	Yes	Yes	Yes	Yes
Patient fixation	Reference is attached to patient head holder Head is fixed to patient stabilization stand	Reference is fixed to patient's bony structure such as a long bone, iliac crest, spinous process, vertebra, etc. for tracking system	Reference is attached to patient head holder	Head is fixed onto robot arm's flange

Performance Testing:
Verification and validation testing was conducted on ExcelsiusGPS® Cranial 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 - cranial 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 cranial devices to the desired location on patient images
- Compliance conformity assessments per:
  - IEC 60601-1 Medical electrical equipment. General requirements for basic safety and essential performance, 2005, Amendment 1, 2012
  - IEC 60601-1-6 Medical Electrical Equipment - Part 1-6, General Requirements for Basic Safety and Essential Performance – Usability
- Navigational accuracy of the subject device system with mean, standard deviation, and 99% confidence interval (CI). Results demonstrate the subject device meets the accuracy acceptance criteria for position and angle as follows:

Position		Angle	
Mean	**99% CI**	**Mean**	**99% CI**
< 1.5mm	≤ 2mm	< 2.0°	≤ 2°

Biocompatibility:
The biocompatibility evaluation for ExcelsiusGPS® has been conducted in accordance with FDA Guidance for Industry and FDA Staff, "Use of International Standard ISO 10993-1, '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.

Electrical Safety and Electromagnetic Compatibility:
Testing was performed to assure compliance with recognized safety standard: IEC 60601-1:2012 standard for electrical safety. Electromagnetic compatibility was not affected.

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® Cranial 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.