August 25, 2021

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

Re: K211616
Trade/Device Name: ExcelsiusHub
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: May 25, 2021
Received: May 26, 2021

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, 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

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)*
K211616

Device Name
ExcelsiusHub™

Indications for Use *(Describe)*
The 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.

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."

510(k) Summary: ExcelsiusHub™ System

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

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

Date Prepared: August 23, 2021

Device Name: ExcelsiusHub™

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: ExcelsiusGPS® Spine 1.1 Interbody Module (K191100)
Excelsius3D™ Imaging System (K210912)

Purpose:
The purpose of this submission is to request clearance for the ExcelsiusHub™.

Device Description:
The ExcelsiusHub™ is a navigation system that includes hardware and software that enables real time surgical visualization using radiological patient images (preoperative CT, intraoperative CT and fluoroscopy), a dynamic reference base, and a camera tracking system. 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. This visualization can help guide the surgeon's planning and approach for implant placement. The patient's scan coupled with the registration provides visual assistance to the surgeon when using the system for free hand navigation. During surgery, the system tracks the position of 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. ExcelsiusHub™ uses the same instruments as ExcelsiusGPS®.

ExcelsiusHub™ may be used in conjunction with ExcelsiusGPS® for guidance of navigated instruments along a planned trajectory using a robotic arm. When connected to ExcelsiusGPS®, ExcelsiusHub™ software is responsible for both navigation and guidance.

Indications for Use:
The 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 ExcelsiusHub™ has similar technological characteristics to the predicate devices including the main system components, workflow, user interface, software features, and design. ExcelsiusHub™ 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 ExcelsiusHub™	Predicate ExcelsiusGPS® (K171651, K191100)
Principle of operation	- Intraoperative/ preoperative images - Patient registration - Surgical planning (optional) - Real-time tracking of navigated instruments - Manual, free hand guidance of instruments	- Intraoperative/ preoperative images - Patient registration - Surgical planning (optional) - Real-time tracking of navigated instruments - Manual, free hand guidance of instruments - Guidance of instruments
Input images	3D preoperative exam 3D intraoperative exam 2D intraoperative exam Excelsius3D™ CT* Excelsius3D™ fluoroscopy*	3D preoperative exam 3D intraoperative exam 2D intraoperative exam
Integrated planning software	ExcelsiusGPS® Planning and Navigation Application Software	ExcelsiusGPS® Planning and Navigation Application Software
Save/load planning	Yes	Yes
Merge images functionality	Yes	Yes
Image-guided	Yes	Yes
Patient registration method	Intra-Op CT: Registration Fixture Pre-Op CT: Fluoroscopic to Pre-Op CT Merge Fluoroscopy: Registration Fixture Excelsius3D™ CT* Excelsius3D™ fluoroscopy*	Intra-Op CT: Registration Fixture Pre-Op CT: Fluoroscopic to Pre-Op CT Merge Fluoroscopy: Registration Fixture

Device	Subject ExcelsiusHub™	Predicate ExcelsiusGPS® (K171651, K191100)
Accuracy verification	Yes	Yes
Real time display of instrument position	Yes	Yes
Patient fixation	Reference is fixed to patient's bony structure such as a long bone, iliac crest, spinous process, vertebra, etc. for tracking system	Reference is fixed to patient's bony structure such as a long bone, iliac crest, spinous process, vertebra, etc. for tracking system

**Excelsius3D 510(k) under FDA review (remove *s and this note upon clearance)*

Performance Testing:

Verification and validation testing were conducted on ExcelsiusHub™ 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
- Qualitative validation to confirm intended use
- Electrical Safety and Electromagnetic Compatibility
  - Testing was performed to assure compliance with recognized safety standards for electrical safety and electromagnetic compatibility
    - IEC 60601-1:2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
    - IEC 60601-1-2:2014 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: *Electromagnetic disturbances*
    - IEC 60601-1-6:2013 Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance - Collateral standard: *Usability*
    - IEC 62304:2015 Medical device software - Software lifecycle processes
    - IEC 62366:2015 Medical devices - Part 1: Application of usability engineering to medical devices

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:

ExcelsiusHub™ 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.