



Food and Drug Administration
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Globus Medical Inc.
Kelly J. Baker, Ph.D.
Senior Vice President, Regulatory and Clinical Affairs
2560 General Armistead Ave.
Audubon, Pennsylvania 19403

August 16, 2017

Re: K171651
Trade/Device Name: EXCELSIUS GPS
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: July 31, 2017
Received: August 1, 2017

Dear Dr. Kelly J. 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K171651

Device Name

EXCELSIUS GPS™

Indications for Use (Describe)

The EXCELSIUS GPS™ 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.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary: EXCELSIUS GPS™

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: June 1, 2017

Device Name: EXCELSIUS GPS™

Common Name: Computer-assisted surgical device

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

Predicates: EXCELSIUS GPS™
Primary predicate: StealthStation (K133444)
Additional predicate: ROSA Spine (K151511)

EXCELSIUS GPS™ Instruments
Additional predicates:
CREO® (K143633)
REVERE® (K133350)
REVOLVE® (K111449)
QUARTEX™ (K161591)
ELLIPSE® (K123783)
SI-LOK® (K112028)
CAPTIVATE™ (K162825)

Purpose:

The purpose of this submission is to request clearance of EXCELSIUS GPS™ and EXCELSIUS GPS™ Instruments.

Device Description:

The EXCELSIUS GPS™ is a Robotic Positioning System that includes a computer controlled robotic arm, hardware, and software that enables real time surgical navigation and robotic guidance using radiological patient images (preoperative CT, intraoperative CT and fluoroscopy), using a dynamic reference base and positioning camera. The navigation and guidance 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, including the end effector of the robotic arm, on the patient images. This visualization can help guide the surgeon's planning and approach. As an aid to visualization, the surgeon can plan implant placement on the patient images prior to surgery. The information of the plan coupled with the registration provides the necessary information to provide visual assistance to the surgeon during free hand navigation or during automatic robotic alignment of the end effector. During surgery, the system tracks the position of GPS compatible instruments, including the end effector of the robotic arm, in or on the patient anatomy and continuously updates the instrument position on patient images utilizing optical tracking. Standard non-navigated metallic instruments that fit through the guide tube at the selected trajectory may be used without navigation while the guide tube is stationary, for uses such as bone preparation (e.g. rongeurs, reamers etc.) or placing implants (e.g. rod inserters, locking cap drivers) that are not related to screw placement. Navigation can also be performed without guidance. System software is responsible for all motion control functions, navigation functions, data storage, network connectivity, user management, case management, and safety functions. EXCELSIUS GPS™ surgical instruments are non-sterile, re-usable instruments that can be operated manually or with the use of the positioning system.

EXCELSIUS GPS™ instruments consist of registration instruments, patient reference instruments, surgical instruments, and end effectors. Registration instruments incorporate arrays of reflective markers, and are used to track patient anatomy and surgical instruments and implants; components include the verification probe, surveillance marker, surgical instrument arrays, intra-op CT registration fixture, fluoroscopy registration fixture, and dynamic reference base (DRB). 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 DRB. Surgical instruments are used to prepare the implant site or implant the device, and include awls, drills, drivers, taps, and probes. End effectors are wirelessly powered guide tubes that attach to the distal end of the robotic arm and provide a rigid structure for insertion of surgical instruments.

Indications for Use:

The EXCELSIUS GPS™ 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.

Technological Characteristics:

The EXCELSIUS GPS™ and EXCELSIUS GPS™ Instruments have similar technological characteristics to the predicate devices including the main system

components, workflow, user interface, software features, and design. The EXCELSIUS GPS™ System is comparable to the predicates in terms of intended use, fundamental scientific technology, technological characteristics and principle of operation. The table below provides a comparison of technological characteristics and principles of operation for the subject EXCELSIUS GPS™ and the predicate devices.

Comparison of Principles of Operation and Technological Characteristics

Device	Subject EXCELSIUS™ GPS	Predicate StealthStation (K133444)	Predicate ROSA Spine (K151511)
Principle of operation	<ul style="list-style-type: none"> - Intraoperative/ preoperative images - Patient registration - Surgical planning - Real-time tracking of navigated instruments - Guidance of instruments 	<ul style="list-style-type: none"> - Intraoperative/ preoperative images - Patient registration - Surgical planning - Real-time tracking of navigated instruments 	<ul style="list-style-type: none"> - Intraoperative images - Patient registration - Surgical planning - Guidance of instruments
Input images	3D pre-operative exam 3D intra-operative exam 2D intra-operative exam	3D pre-operative exam 3D intra-operative exam 2D intra-operative exam	3D intra-operative exam
Integrated planning software	EXCELSIUS™ GPS Planning and Navigation Application software	Synergy Spine software	Rosanna Spine (Medtech)
Save/load planning	Yes	Yes	Yes
Merge images functionality	Yes	Yes	Yes
Trajectory planning parameters	Entry point, target point, instrument length/diameter	Entry point, target point, instrument length/diameter	Entry point, target point, instrument length/diameter
Localization means	Optical system (infrared camera)	Optical (infrared camera) or electromagnetic system	Robot arm absolute encoders and optical system (infrared camera)
Image-guided	Yes	Yes	Yes
Controller	Force-controlled movement allowing robotic arm positioning	No controller; instruments are manually positioned by the surgeon.	Axis controller per joint Kinematic transformation Supervisor module
Patient registration method	Intra-op CT: Registration fixture Pre-op CT: Fluoroscopic to pre-op CT merge Fluoroscopy: Registration fixture	Point-to-point registration with anatomical markers Intra-op CT: Calibrated CT gantry to camera merge Pre-op CT: Point merge Fluoroscopy: Registration fixture	3D registration with X-Ray pattern containing radiopaque markers
Accuracy verification on anatomical landmarks	Yes (probe)	Yes (probe)	Yes (probe)
Real time display of instrument position	Yes	Yes	Yes

Device	Subject EXCELSIUS™ GPS	Predicate StealthStation (K133444)	Predicate ROSA Spine (K151511)
Provide guide for instruments	Yes, instruments are used through the guide tube on the robotic arm or are manually positioned by the surgeon.	No, instruments are manually positioned by the surgeon.	Yes, instruments are mounted onto the robotic arm.
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 the patient's iliac crest or clamped on the spinous for tracking system	Reference is fixed to the patient's iliac crest for tracking system

Performance Testing:

Verification and validation testing was conducted on EXCELSIUS GPS™ 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
- Surgical simulations conducted on phantom models
- Human cadaveric quantitative validation under clinically relevant scenarios
- Compliance conformity assessments per:
 - IEC 60601-1 Medical electrical equipment. General requirements for basic safety and essential performance, 2005, Amendment 1, 2012
 - IEC 60601-1-2 Medical Electrical Equipment – Part 1-2, General Requirements for Basic Safety and Essential Performance – Collateral Standard Electromagnetic Compatibility, 2007
 - IEC 60601-1-6 Medical Electrical Equipment - Part 1-6, General Requirements for Basic Safety and Essential Performance - Usability

Biocompatibility:

The biocompatibility evaluation for EXCELSIUS GPS™ 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 EXCELSIUS GPS meets biocompatibility requirements.

Electrical Safety and Electromagnetic Compatibility:

Testing was performed to assure compliance with recognized safety standards: IEC 60601-1:2012 standard for electrical safety and IEC 60601-1-2:2014 standard for electromagnetic compatibility.

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) and IEC 62304:2006-05 Medical Device Software – Software life cycle processes. The software for this device is considered a “MAJOR” level of concern.

Basis of Substantial Equivalence:

EXCELSIUS GPS™ 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.