February 6, 2019

Globus Medical Inc.
Ms. Lori Burns
Director, Regulatory Affairs
Valley Forge Business Center
2560 General Armistead Avenue
Audubon, Pennsylvania 19403

Re: K183119
Trade/Device Name: SI-LOK® Sacroiliac Joint Fixation System, Navigation Instruments, ExcelsiusGPS® Instruments
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: OUR, OLO
Dated: November 8, 2018
Received: November 9, 2018

Dear Ms. Burns:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ronald P. Jean -S

for Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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)*
K183119

Device Name
SI-LOK® Sacroiliac Joint Fixation System

Indications for Use *(Describe)*
The SI-LOK® Sacroiliac Joint Fixation System is intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

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)*
K183119

Device Name
Navigation Instruments

Indications for Use *(Describe)*
Globus Navigation Instruments are intended to be used during the preparation and placement of Globus screws (QUARTEX®, CREO®, REVERE®, REVOLVE®, ELLIPSE®, PROTEX® CT, and SI-LOK®) during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. These instruments are designed for use with the Medtronic StealthStation System, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as a skull, a long bone, or vertebra, can be identified relative to a CT or MRI based model, fluoroscopy images, or digitized landmarks of the anatomy.

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)

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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)*
K183119

Device Name
ExcelsiusGPS®

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.

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)

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510(k) Summary: SI-LOK® Additional Implants and Instruments

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

Contact:
Lori Burns
Director, Regulatory Affairs

Date Prepared: November 8, 2018

Device Name:
SI-LOK® Sacroiliac Joint Fixation System
Navigation Instruments
ExcelsiusGPS® Instruments

Common Name:
Sacroiliac Joint Fusion System
Navigation Instruments

Classification:

SI-LOK® Sacroiliac Joint Fixation System
Per 21 CFR as follows:
§888.3040: Smooth or threaded metallic bone fixation fastener
Product Code: OUR
Regulatory Class: II, Panel Code: 87

Navigation Instruments
Per 21 CFR as follows:
§882.4560 Stereotaxic Instruments
Product Code OLO
Regulatory Class: II, Panel Code: 84

ExcelsiusGPS® Instruments
Per 21 CFR as follows:
§882.4560 Stereotaxic Instruments
Product Codes OLO
Regulatory Class: II, Panel Code: 87

Primary Predicate: SI-LOK® Sacroiliac Joint Fixation System (K112028)

Additional Predicates:
Synthes Cannulated Screw System (K962011, K021932)
Medtronic RIALTO (K161210)

SI-LOK® ExcelsiusGPS® Instruments
ExcelsiusGPS® (K171651)

SI-LOK® Navigation Instruments
Navigation Instruments (K153203, K180690)

Purpose:
The purpose of this submission is to request clearance of additional SI-LOK® Select implants, ExcelsiusGPS® Instruments, and Navigation Instruments.

Device Description:
The SI-LOK® Sacroiliac Joint Fixation System (including SI-LOK® Select) consists of cannulated, fully or partially threaded screws that are available with or without slots and optional pre-assembled contouring washers. One, two or three screws may be placed in one sacroiliac joint, depending on the approach.

The screws and washers are manufactured from titanium alloy, as specified in ASTM F136 (Ti6AI4V) and F1295 (Ti6AI7Nb). SI-LOK® screws are available with or without hydroxyapatite (HA) coated, as specified in ASTM F1185.

SI-LOK® Sacroiliac Joint Fixation System include surgical instruments manufactured from stainless steel, as specified in ASTM F899.

SI-LOK® ExcelsiusGPS® Instruments are nonsterile, reusable instruments that can be operated with the ExcelsiusGPS® robotic arm, or may be used for a freehand navigated surgical procedure.

SI-LOK® Navigation Instruments are nonsterile, reusable instruments that can be operated manually or under power using a power drill such as POWEREASE that are intended to be used with the Medtronic StealthStation® System.

Indications for Use:

SI-LOK® Sacroiliac Joint Fixation System
The SI-LOK® Sacroiliac Joint Fixation System is intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis.

ExcelsiusGPS® Instruments
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.

Navigation Instruments

Globus Navigation Instruments are intended to be used during the preparation and placement of Globus screws (QUARTEX®, CREO®, REVERE®, REVOLVE®, ELLIPSE®, PROTEX®-CT, and SI-LOK®) during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. These instruments are designed for use with the Medtronic StealthStation System, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as a skull, a long bone, or vertebra, can be identified relative to a CT or MRI based model, fluoroscopy images, or digitized landmarks of the anatomy.

Performance Data:

Mechanical testing, including static and dynamic cantilever bending and screw pull-out, were conducted in accordance with ASTM F2193 and ASTM F543 to demonstrate substantial equivalence of the subject SI-LOK Select implants to the predicate devices. Accuracy testing performed on the predicate Navigation instruments is applicable for the subject instruments and has not been repeated. Bacterial endotoxin testing (BET) was conducted in accordance with ANSI/AAMI ST-72:2011. Biocompatibility of patient-contacting materials was demonstrated by using materials that meet applicable standards or are used in 510(k) cleared devices.

Technological Characteristics:

Subject SI-LOK® Select implants, ExcelsiusGPS® instruments, and Navigation instruments have the same technological characteristics as the predicate devices including design, intended use, material composition, function, and range of sizes.

Basis of Substantial Equivalence:

The subject SI-LOK® implants and instruments are similar to the predicate devices with respect to technological characteristics, performance, design, and intended use. The information provided within this premarket notification supports substantial equivalence to the predicate devices.