March 7, 2018

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

Re: K180156
Trade/Device Name: SP-Fix® Spinous Process Fixation Plate,
RELIEVE® Laminoplasty Fixation System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: Class II
Product Code: PEK, NQW
Dated: January 18, 2018
Received: January 19, 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. 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.

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.

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)*
K180156

Device Name
SP-Fix® Spinous Process Fixation Plate

Indications for Use *(Describe)*
The SP-Fix® Spinous Process Fixation Plate is a posterior non-pedicle supplemental fixation device, intended for use at a single level in the non-cervical spine (T1–S1). It is intended for plate fixation/attachment to the spinous processes for the purpose of achieving supplemental fusion in the following conditions: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), and/or tumor. The SP-Fix® Spinous Process Fixation Plate is intended for use with allograft or autograft bone and is not intended for stand-alone use.

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:

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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)*
K180156

Device Name
RELIEVE® Laminoplasty Fixation System

Indications for Use *(Describe)*
The RELIEVE® Laminoplasty Fixation System is intended for use in the lower cervical and upper thoracic spine (C3-T3) in laminoplasty procedures. The RELIEVE® Laminoplasty Fixation System is used to hold the allograft or autograft bone in place in order to prevent the graft from expulsion, or impinging the spinal cord.

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.

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510(k) Summary: Additional PEEK Devices

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

Contact: Lori Burns
Director, Regulatory Affairs

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

Date Prepared: January 18, 2018

Device Name: SP-Fix® Spinous Process Fixation Plate
RELIEVE® Laminoplasty Fixation System

Common Name: Spinal Interlaminal Fixation Orthosis

Classification: Per 21 CFR as follows:
§888.3050 Spinal Interlaminal Fixation Orthosis
Product Code(s):
PEK: SP-FIX®
NQW: RELIEVE®
Regulatory Class: II, Panel Code: 87

Primary Predicates: SP-Fix® Spinous Process Fixation Plate (K102195, K132191)
RELIEVE® Laminoplasty Fixation System (K080664)

Predicates: HAVEN® Laminoplasty System (K171413)
Kalitec Direct InSePtion MIS Fixation System (K163471)

Reference Device: Anterior Spinal Devices PEEK (K152022)

Purpose:
The purpose of this submission is to request clearance for an additional PEEK vendor and to update indications for SP-Fix® and RELIEVE®.

Device Description:
SP-Fix®
The SP-Fix® Spinous Process Fixation Plate consists of plates, rods and barrels that are used to build a construct to provide supplemental stabilization of spinal segments to support fusion. The components are available in a range of sizes to fit the anatomical needs of a variety of patients.

RELIEVE®
The RELIEVE® Laminoplasty Fixation System consists of spinal fixation plates and screws for use in laminoplasty procedures. RELIEVE® implants are inserted through a posterior cervical or thoracic approach, and are available in various sizes and geometric options to fit individual patient anatomy. Plates may be filled with bone graft material. Screws are used to attach the plates to bone and are available in a variety of lengths and diameters to fit patient anatomy.

Indications for Use:
SP-Fix®
The SP-Fix® Spinous Process Fixation Plate is a posterior non-pedicle supplemental fixation device, intended for use at a single level in the non-cervical spine (T1–S1). It is intended for plate fixation/attachment to the spinous processes for the purpose of achieving supplemental fusion in the following conditions: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), and/or tumor. The SP-Fix® Spinous Process Fixation Plate is intended for use with allograft or autograft bone and is not intended for stand-alone use.

RELIEVE®
The RELIEVE® Laminoplasty Fixation System is intended for use in the lower cervical and upper thoracic spine (C3-T3) in laminoplasty procedures. The RELIEVE® Laminoplasty Fixation System is used to hold the allograft or autograft bone in place in order to prevent the graft from expulsion, or impinging the spinal cord.

Performance Data:
Globus is not aware of any performance standards or special control as established to date for the above device or product code. Testing was conducted in accordance with the “Guidance for Industry and FDA Staff, Guidance for Spinal System 510(k)s”, May 3, 2004. Static and Dynamic Compression and Static Cantilever Bending testing performed on the RELIEVE® plates demonstrates substantial equivalence to the predicate devices. No additional mechanical testing for SP-Fix® plates was performed.

No further sterilization, biocompatibility and endotoxin evaluation and/or testing were required for this submission.

Technological Characteristics:
SP-Fix® and RELIEVE® implants have the same technological characteristics as the predicate devices including design, intended use, material composition, function, and range of sizes.

Basis of Substantial Equivalence:

SP-Fix® and RELIEVE® implants have 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 of the subject devices to the predicate devices.