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510(k) Summary: SP-Fix® Spinous Process Fixation Plate

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

Contact: Christina Kichula
Regulatory Affairs Group Manager

Date Prepared: July 12, 2013

Device Name: SP-Fix® Spinous Process Fixation Plate

Classification: Per 21 CFR as follows:
§888.3050 Spinal Interlaminal Fixation Orthosis
Product Code: PEK
Regulatory Class: Class II, Panel Code 87.

Predicate(s): SP-Fix® Spinous Process Fixation Plate (K102195)
Medtronic SPIRE® (K032037)

Purpose:
The purpose of this submission is to request clearance for additional SP-Fix® implants, including taller barrels and additional plate options.

Device Description:
The SP-Fix® Spinous Process Fixation Plate System 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. SP-Fix® implants are composed of titanium alloy (per ASTM F136) and PEEK radiolucent polymer (per ASTM F2026).

Indication for Use:
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 bone graft material and is not intended for stand-alone use.

Technological Characteristics:
The technological characteristics of the additional SP-Fix® implants are similar to the predicate devices in terms of design, dimensions, intended use, materials, and performance characteristics.

Performance Data:
Mechanical testing (static plate dissociation) was conducted and an engineering rationale was provided to demonstrate substantial equivalence to the predicate system.

Basis of Substantial Equivalence:
The additional SP-Fix® implants have been demonstrated to be substantially equivalent to predicate systems with respect to technical characteristics, performance, and intended use. The information provided within this premarket notification supports substantial equivalence to the predicate devices. Additional SP-Fix® implants perform as well as or better than the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

November 22, 2013

Globus Medical, Incorporated
Ms. Christina Kichula
Regulatory Affairs Group Manager
2560 General Armistead Avenue
Audubon, Pennsylvania 19403

Re: K132191
Trade/Device Name: SP-Fix® Spinous Process Fixation Plate
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: Class II
Product Code: PEK
Dated: September 30, 2013
Received: October 1, 2013

Dear Ms. Kichula:

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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 yours,

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 Statement

510(k) Number: K132191

Device Name: SP-Fix® Spinous Process Fixation Plate

INDICATIONS:

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 bone graft material and is not intended for stand-alone use.

Prescription Use __X__ OR Over-The-Counter Use___
(Per 21 CFR §801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ronald P. Jean -S

(Division Sign-Off)
Division Of Orthopedic Devices
510(k) Number: K132191