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

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

Contact: Kelly J. Baker, Ph.D
Director, Clinical Affairs & Regulatory

JAN 19 2011

Date Prepared: November 10, 2010

Device Name: SP-Fix™ Spinous Process Fixation Plate

Classification: Regulation Number: 21 CFR §888.3050
Regulation Name: Spinal Interlaminal Fixation Orthosis
Product Code: KWP
Regulatory Class II, Panel code 87.

Predicate(s): Medtronic Spire™ (K032037), LANX Aspen™ (K071877), NuVasive AFFIX™ (K073278)

Purpose:
The purpose of this submission is the addition of the SP-Fix™ Spinous Process Fixation Plate to the REVERE® Stabilization System.

Device Description:
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. SP-Fix™ implants are composed of titanium alloy (per ASTM F136) and PEEK radiolucent polymer (per ASTM F2026).

Indications 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.

Performance Data:
Mechanical testing (static and dynamic compression, static torsion, static and dynamic plate dissociation, and static tension) was conducted to demonstrate substantial equivalence to the predicate system(s).

Basis of Substantial Equivalence:
The SP-Fix™ has been demonstrated to be substantially equivalent to predicate system(s) with respect to technical characteristics, performance, and intended use. The information provided within this premarket notification supports substantial equivalence of the subject device to the predicate device(s).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

JAN 19 2011

Globus Medical, Inc.
% Kelly J. Baker, Ph.D.
Director, Clinical Affairs and Regulatory
Valley Forge Business Center
2560 General Armistead Avenue
Audubon, Pennsylvania 19403

Re: K102195
Trade 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: KWP
Dated: December 30, 2010
Received: January 03, 2011

Dear Dr. 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K102195

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)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K102195