DEC - 9 2011

K112028

510(k) SUMMARY: SI-LOK™ Sacroiliac Joint Fixation System

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

Contact: Wendy S. Hills
Project Manager, Regulatory Affairs

Date Prepared: July 13, 2011

Device Name: SI-LOK™ Sacroiliac Joint Fixation System

Classification: Per 21 CFR as follows:
§888.3040: Smooth or threaded metallic bone fixation fastener
Product Codes: HWC, OUR
Regulatory Class: II, Panel Code: 87

Predicate(s): Synthes Cannulated Screw (K021932)
SE date: September 6, 2002, re-evaluated April 7, 2011
Synthes Cannulated Screw (K962011)
SE date: August 5, 1996
DePuy Spine SIJF Cannulated Screw System (K051296)
SE date: August 26, 2005, re-evaluated April 7, 2011
Zyga Technology SImmetry Joint Fusion System (K111801, K110512)
SE date: July 21, 2011, March 23, 2011

Purpose:
The purpose of this submission is to request clearance for the SI-LOK™ Sacroiliac Joint Fixation System.

Device Description:
The SI-LOK™ Sacroiliac Joint Fixation System consists of screws designed to enhance sacroiliac joint fusion and to provide fixation of large bones and large bone fragments of the pelvis. The cannulated partially threaded or fully threaded screws contain a pre-assembled contouring washer, and are offered in various diameters and lengths to accommodate patient anatomy. Optional screws may be used for supplemental screw fixation.

The SI-LOK™ Sacroiliac Joint Fixation System screws and pre-assembled contouring washers are manufactured from titanium alloy, as specified in ASTM F136 and F1295. The screws are available with or without hydroxyapatite (HA) coated, as specified in ASTM F1185.

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

Performance Data:
Mechanical testing, including static and dynamic cantilever bending and screw insertion and pull-out were conducted to demonstrate substantial equivalence to the predicate devices.

Basis for Substantial Equivalence:
The SI-LOK™ Sacroiliac Joint Fixation System is substantially equivalent to legally marketed predicate devices in terms of indications, design, materials, and performance.

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

Globus Medical
% Ms. Wendy S. Hills
Project Manager, Regulatory Affairs
2560 General Armistead Avenue
Audubon, Pennsylvania 19403

DEC - 9 2011

Re: K112028
Trade/Device Name: SI-LOK™ Sacroiliac Joint Fixation System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC, OUR
Dated: December 1, 2011
Received: December 2, 2011

Dear Ms. Hills:

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.

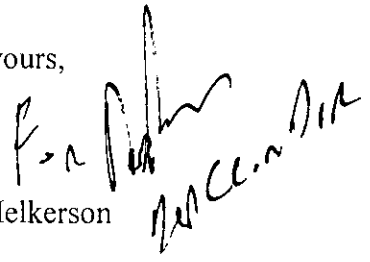
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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: K112028

Device Name: SI-LOK™ Sacroiliac Joint Fixation System

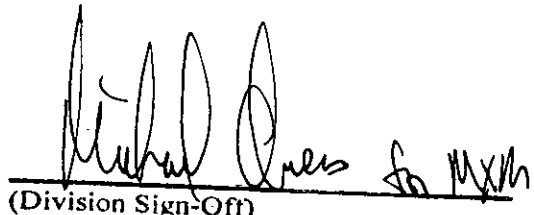
Indications:

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

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 K112028