K090952

510(k) SUMMARY: ZYFUSE™ Facet Fixation System

JUL 14 2009

Company: Globus Medical Inc.
2560 General Armistead Ave.
Audubon, PA 19403
(610) 415-9000

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

Device Name: ZYFUSE™ Facet Fixation System

Classification: Product Code MRW. Unclassified.

Predicate(s): CORRIDOR Fixation System (K083442)

Device Description:
The ZYFUSE™ Facet Fixation System consists of screws designed to compact juxtaposed facet articular processes to enhance spinal fusion. The cannulated, partially threaded screws are available with or without a washer, and in various diameters and lengths to accommodate patient anatomy. The ZYFUSE™ Facet Fixation System implants are fabricated from medical grade titanium alloy as specified in ASTM F136, F1295 and HA coated as specified in ASTM F1185. Due to the risk of galvanic corrosion following implantation, titanium alloy implants should not be used in the same construct as stainless steel implants.

Intended Use:
The ZYFUSE™ Facet Fixation System is intended to stabilize the spine as an aid to fusion through bilateral immobilization of the facet joints, with or without bone graft, at single or multiple levels, from L1 to S1. For transfacet fixation, the screws are inserted posteriorly through the superior side of the facet, across the facet joint, and into the pedicle. For translaminar facet fixation, the screws are inserted posteriorly through the lateral aspect of the spinous process, through the lamina, through the superior side of the facet, across the facet joint, and into the pedicle.

The ZYFUSE™ Facet Fixation System is indicated for treatment of any or all of the following: pseudoarthrosis and failed previous fusions which are symptomatic or which may cause secondary instability or deformity; spondylolisthesis; spondylolysis; degenerative disc disease (DDD) as defined by neck and/or back pain of discogenic origin as confirmed by radiographic studies; degeneration of the facets with instability and trauma including spinal fractures and/or dislocations.

Basis for Substantial Equivalence:
The ZYFUSE™ Facet Fixation System is similar in terms of indications, design, materials, and performance, to currently marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 14 2009

Globus Medical, Inc.
% Kelly J. Baker, Ph.D.
2650 General Armistead Ave., Valley Forge
Audubon, PA 19403

Re: K090952
Trade/Device Name: Zyfuse Facet Fixation System
Regulation Number: N/A
Regulation Name: N/A
Regulatory Class: Unclassified
Product Code: MRW
Dated: May 18, 2009
Received: May 19, 2009

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.

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 (240) 276-3150 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: K090952

Device Name: ZYFUSE™ Facet Fixation System

Indications:

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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)

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

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