



Food and Drug Administration
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August 26, 2014

Globus Medical, Incorporated
Kelly J. Baker, Ph.D.
Senior Vice President, Regulatory and Clinical Affairs
2560 General Armistead Avenue
Audubon, Pennsylvania 19403

Re: K133678
Trade/Device Name: CONFIRM™ Bioactive
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: August 19, 2014
Received: August 20, 2014

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 contact the Division of Industry and Consumer Education 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 Industry and Consumer Education 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,

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

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

Indications for Use

510(k) Number (if known)
K133678

Device Name
CONFIRM™ Bioactive

Indications for Use (Describe)

CONFIRM™ Bioactive is intended for use as a bone void filler and autograft extender for voids or gaps that are not intrinsic to the stability of the bony structure. These osseous defects may be surgically created or created from traumatic injury to the bone. CONFIRM™ Crunch is intended to be gently packed into bony voids or gaps of the skeletal system (i.e., the extremities, pelvis, and posterolateral spine) and must be combined with bone marrow aspirate and autogenous bone graft. CONFIRM™ Putty, Plus Putty, Gel, Plus Gel, and Plus Crunch are intended to be gently packed into bony voids or gaps of the skeletal system (i.e., the extremities and pelvis) and must be combined with bone marrow aspirate and autogenous bone graft. CONFIRM™ resorbs and is replaced with bone during the healing process.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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:

Department of Health and Human Services
Food and Drug Administration
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Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

“An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.”

510(k) Summary: CONFIRM™ Bioactive

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

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

Date Prepared: August 25, 2014

Device Name: CONFIRM™ Bioactive

Classification: Per 21 CFR as follows:
§888.3045 Resorbable Calcium Salt Bone Void Filler
Device
Product Codes: MQV
Regulatory Class: II, Panel Code 87

Predicate(s): KINEX™ Bioactive Bone Void Filler, K130392
Vitoss® BA Bioactive Bone Graft Substitute, K103173 &
K994337
NovaBone® Bioactive Bone Graft, K080009

Purpose:

The purpose of this submission is to request clearance of the CONFIRM™ Bioactive.

Device Description:

CONFIRM™ Bioactive is a resorbable bone void filler for the repair of bony defects. It is an osteoconductive and osteostimulative material that guides bone regeneration. When CONFIRM™ is placed in direct contact with host bone, new bone grows in apposition to the implant. As the implant resorbs, bone and other connective tissues grow into the space previously occupied by CONFIRM™.

CONFIRM™ consists of Bioglass (per ASTM F1538), hyaluronic acid, and glycerol, and is available in putty, gel, and crunch forms to accommodate surgical and anatomical needs.

Indications for Use:

CONFIRM™ Bioactive is intended for use as a bone void filler and autograft extender for voids or gaps that are not intrinsic to the stability of the bony structure. These osseous defects may be surgically created or created from traumatic injury to the bone. CONFIRM™ Crunch is intended to be gently packed into bony voids or gaps of the skeletal system (i.e., the extremities, pelvis, and

posterolateral spine) and must be combined with bone marrow aspirate and autogenous bone graft. CONFIRM™ Putty, Plus Putty, Gel, Plus Gel, and Plus Crunch are intended to be gently packed into bony voids or gaps of the skeletal system (i.e., the extremities and pelvis) and must be combined with bone marrow aspirate and autogenous bone graft. CONFIRM™ resorbs and is replaced with bone during the healing process.

Performance Data:

In vivo performance testing (tibial defect model and posterolateral spine fusion model) and biocompatibility testing were conducted in accordance with the “Guidance for Industry and FDA Staff; Class II Special Controls Guidance Document: Resorbable Calcium Salt Bone Void Filler Device,” June 2, 2003. Performance data demonstrates substantial equivalence to the predicate devices.

Basis of Substantial Equivalence:

CONFIRM™ Bioactive is similar to the predicate devices with respect to technical characteristics, performance, and intended use. The information provided within this premarket notification supports substantial equivalence to the predicate device(s). CONFIRM™ implants are as safe, as effective, and perform as well as or better than the predicate devices.