510(k) Summary

BioStructures, LLC

Interface Bone Void Filler

September 29, 2011

ADMINISTRATIVE INFORMATION

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DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	Interface Bone Void Filler
Common Name:	Bone void filler
Classification Regulations:	21 CFR 888.3045, Class II
Product Code:	MQV
Classification Name:	Filler, bone void, calcium compound
Classification Panel:	Orthopaedic and Rehabilitation Devices Panel
Reviewing Branch:	Restorative Devices Branch

INTENDED USE

Interface Bone Void Filler is indicated for bony voids or gaps that are not intrinsic to the stability of the bony structures. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. Interface Bone Void Filler is indicated to be gently packed into bony voids or gaps of the skeletal system (extremities and pelvis), or in the posterolateral spine when mixed with autograft. The product provides a bone void filler that resorbs and is replaced with bone during the healing process.

DEVICE DESCRIPTION

Interface Bone Void Filler is a synthetic bioactive bone graft for use in the repair of osseous defects. It is supplied as irregular synthetic granules of bioactive glass, sized from 200 microns to 420 microns. The elemental composition of Interface Bone Void Filler granules is Si, Ca, Na, and P. Interface Bone Void Filler conforms to ASTM specification F1538 for 45S5 bioactive glass.

EQUIVALENCE TO MARKETED DEVICE

BioStructures, LLC submits the following information in this Premarket Notification to demonstrate that, for the purposes of FDA's regulation of medical devices Interface Bone Void Filler is substantially equivalent in indications and design principles to the following predicate devices, each of which has been determined by FDA to be substantially equivalent to pre-amendment devices:

BioStructures LLC, Interface Bone Void Filler, cleared under K092541; and

NovaBone Products, LLC, NovaBone Resorbable Bone Graft Substitute, cleared under K021336.

The subject device and the predicate devices have the same intended use and have the same technological characteristics. The subject device and the predicate devices are synthetic bioactive glass with elemental composition of Si, Ca, Na, and P. The subject device and the predicate devices have similar particle sizes, and are packaged in similar materials and sterilized using similar methods.

To demonstrate equivalence detailed side-by-side material characterization was performed including chemical composition, physical properties and performance characteristics. Chemical composition was analyzed by scanning electron microscopy with energy dispersive x-ray analysis (SEM/EDXA). Trace elemental analysis was performed by inductively coupled plasma/optical emission spectroscopy (ICP/OES). Crystallinity was analyzed by Fourier Transform Infrared Spectroscopy (FT-IR) and X-ray Diffraction (XRD). Physical properties were evaluated by scanning electron microscopy and particle size was determined by laser diffraction. Dissolution testing was performed by monitoring the concentration of calcium in

media by a calcium-specific electrode in an appropriate dissolution apparatus. The analytical characterization demonstrated equivalent chemical composition, physical properties and performance characteristics for the Interface Bone Void Filler and the NovaBone Resorbable Bone Graft Substitute devices.

The radiographic, morphometric and histologic performance of the subject Interface Bone Void Filler device were compared to that of the predicate NovaBone device in a posterolateral spine fusion animal model. The results of the study demonstrated that the performance of the subject Interface Bone Void Filler device was equivalent to that of the predicate NovaBone device.

Interface Bone Void Filler has the following similarities to the predicate devices:

- has the same intended use,
- uses the same operating principle,
- incorporates the same basic design,
- incorporates the same or very similar materials, and
- has similar packaging and is sterilized using the same processes.

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

DEC 13 2011

BioStructures, LLC
% PaxMed International, LLC
Kevin A. Thomas, PhD
11234 El Camino Real, Suite 200
San Diego, California 92130

Re: K112857
Trade/Device Name: Interface Bone Void Filler
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: September 29, 2011
Received: September 30, 2011

Dear Dr. Thomas:

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

510(k) Number: K112857

Device Name: Interface Bone Void Filler

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Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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