



Berkeley Advanced Biomaterials
François Génin, Ph.D.
Chief Executive Officer
901 Grayson Street, Suite 101
Berkeley, California 94710

October 30, 2017

Re: K170917

Trade/Device Name: Bi-Ostetic Bioactive Glass Foam
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: September 25, 2017
Received: September 29, 2017

Dear Dr. Génin:

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 (DICE) 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 (DICE) 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,


Mark N. Melkerson -S

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 below.

Indications for Use

510(k) Number (if known)
K170917

Device Name
Bi-Ostetic Bioactive Glass Foam

Indications for Use (Describe)

Bi-Ostetic Bioactive Glass Foam is indicated for use in bony voids or gaps of the skeletal system (i.e. extremities, pelvis and posterolateral spine). These osseous defects are surgically created or result from traumatic injury to the bone, and are not intrinsic to the stability of the bony structure. The graft resorbs and is replaced by the growth of new bone during the healing process. Bi-Ostetic Bioactive Glass Foam must be used with autogenous bone marrow aspirate and autograft in the posterolateral spine.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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
Office of Chief Information Officer
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.”

BERKELEY ADVANCED BIOMATERIALS

901 Grayson Street, Suite 101, Berkeley, CA 94710, USA
Tel: (510) 883 0500; Fax: (510) 883 0511
<http://www.ostetic.com>



510(K) Summary – Bi-Ostetic Bioactive Glass Foam

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807, this information serves as a Summary of Safety and Effectiveness for the use of the device.

| | |
|--------------------------|---|
| Submitted By: | Berkeley Advanced Biomaterials |
| Date: | 27 March 2017 |
| Contact Person: | François Génin, Ph.D. |
| Position: | Chief Executive Officer |
| Contact Information | Phone: 510-883-0500; Fax: 510-883-0511 |
| Proprietary Name: | Bi-Ostetic Bioactive Glass Foam |
| Regulation Name: | Resorbable Calcium Salt Bone Void Filler Device |
| Regulation Number: | 888.3045 |
| Classification: | Class II |
| Device Code/ Panel Code: | Orthopedics/87/MQV |

DEVICE INFORMATION

A. INTENDED USE

Bi-Ostetic Bioactive Glass Foam is indicated for use in bony voids or gaps of the skeletal system (i.e. extremities, pelvis and posterolateral spine). These osseous defects are surgically created or result from traumatic injury to the bone, and are not intrinsic to the stability of the bony structure. The graft resorbs and is replaced by the growth of new bone during the healing process. Bi-Ostetic Bioactive Glass Foam must be used with autogenous bone marrow aspirate and autograft in the posterolateral spine.

B. DEVICE DESCRIPTION

The device is a bone void filler consisting of a collagen matrix mineralized with hydroxyapatite (HA) - tri-calcium phosphate (TCP) granules and 45S5 bioactive glass granules. The bovine fibrillar collagen component is biocompatible. The 45S5 glass particles are bioactive. The device is available in the form of granules, strips and putty. The composition of the granules is 60 wt% HA and 40 wt% TCP. The amount of 45S5 granules in the graft is 20 wt%. When used in the extremities, the granules and strips can be hydrated with sterile water and blood (nominally 1:1). When used in the posterolateral spine, the graft material must be hydrated with bone marrow aspirate (1:1 ratio), then mixed with autograft bone (1:1 ratio). The defect site should be filled as completely as possible. The device provides a scaffold around which new bone can grow. A series of surface reactions on the particles results in the formation of a calcium phosphate layer that is substantially equivalent in composition and structure to the hydroxyapatite found in bone mineral. This apatite layer on the 45S5 granules and the hydroxyapatite- tri-calcium phosphate granules provide an osteoconductive scaffold onto which the patient's new bone will grow. During healing, the graft particulate is absorbed and remodeled into new bone.

C. SUBSTANTIAL EQUIVALENCE INFORMATION

The intended use, materials and design features of the device are substantially equivalent to the predicate devices FormaGraft and Bi-Ostetic Foam. Bi-Ostetic Bioactive Glass Foam has the

same classification as the predicate devices. It has the same intended use and the same or similar technological characteristics, principles of operation and indications as the predicate devices. FormaGraft, Bi-Ostetic Foam and Bi-Ostetic Bioactive Glass Foam all contain the same HA-TCP granules and similar amounts of bovine collagen. Bi-Ostetic Bioactive Glass is provided in strip and putty forms like the Bi-Ostetic Foam (FormaGraft comes only as strips). Device dosage, packaging and sterilization methods are the same as Bi-Ostetic Foam. Bi-Ostetic Bioactive Glass Foam can be mixed with autogenous bone marrow like FormaGraft (Bi-Ostetic Foam is mixed with blood or saline). The safety and effectiveness of the devices are adequately supported by the substantial equivalence information provided within the Premarket Notification and as demonstrated by comparative evaluation in animal studies.

D. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The chemistry and specifications of the granules (hydroxyapatite - beta tri-calcium phosphate and 45S5 bioactive glass) in a collagen matrix are substantially equivalent to the predicate device. Testing of the chemistry of the components was performed by FTIR and X-Ray Diffraction analysis. The purity of the components was measured by ICP-MS. Physical properties were evaluated by Scanning Electron Microscopy (SEM). Sterilization is performed according to ISO 11137 standards. Bi-Ostetic BGF Foam is Bi-Ostetic Foam (K092046) in which part of the HA-TCP granules has been substituted with 45S5 granules. Bi-Ostetic BGF Foam is also similar in characteristics to FormaGraft (K050789). The radiographic, morphometric and histologic performance of the device was compared to that of the predicate.

E. PERFORMANCE DATA

In vivo and *in vitro* testing of the device in accordance to ISO 10993 Biological Evaluation of Medical Devices has demonstrated that the materials are safe and biocompatible. The device is considered bioactive based on *in vitro* studies that show apatite layer formation on the surface of the bioactive glass particles following immersion in simulated body fluid (SBF). The device was tested to establish non-pyrogenicity according ISO 10993-11. Limulus Amebocyte Lysate (LAL) batch testing demonstrated that bacterial endotoxin levels were below the standard 0.5EU/mL and 20EU/device in accordance with ANSI/AAMI ST72(2002), and ISO 10993-11. The performance of the device in postero-lateral spine fusion and femoral cancellous defect animal models was compared to the performance of FormaGraft. The results showed substantial equivalence with FormaGraft.

Test results have not been correlated to clinical performance. The results are consistent with the literature and previous laboratory results for this model. The conclusions drawn from the nonclinical tests demonstrate that the device is as safe, as effective, and performs as well as or better than the predicate devices.