JAN 3 0 2003 K023703

BERKELEY ADVANCED BIOMATERIALS, INC.
1933 Davis Street, Suite 307, San Leandro, CA 94577, USA
Tel: (510) 883 1644; Fax: (510) 883 1315
Email: info@hydroxyapatite.com
http://www.hydroxyapatite.com

ISO9001:94/EN4600

510(K) Summary Statement for Bi-Ostetic™

In accordance with the Food and Drug Admisnistration 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 Bi-Ostetic™ Bone Void Filler.

Submitted By:	Berkeley Advanced Biomaterials, Inc.
Date:	30 October 2002
Contact Person:	François Génin, Ph.D.
Position:	President and CEO
Contact Information	Phone: 510-883-1644; Fax: 510-883-1315
Proprietary Name:	Bi-Ostetic™
Common Name:	Bone Void Filler
Classification Name and Reference	Unclassified
Device Product Code and Panel Code	Orthopedics/87/MQV

DEVICE INFORMATION

A. INTENDED USES/INDICATIONS

Bi-Ostetic™ is an osteoconductive bone substitute shaped as granules or blocks (cancellous, cortical or cortico-cancellous) that are intended to be used to fill voids and gaps that are not intrinsic to the stability of the bone structure. These gaps or voids may be located in the extremities, spine, pelvis, or cranium.
The granules or blocks may be pressed into the void or into the surgical site by hand. The Bi-Ostetic™ granules or blocks provide void filling material that acts as a temporary support medium. The granules or blocks are not intended to provide structural support during the healing process. The implant is radio-opaque. Bi-Ostetic™ is biocompatible and resorbs in the body as bone ingrowth occurs.

B. DEVICE DESCRIPTION

Bi-Ostetic™ is a sterile osteoconductive bone void filler. It consists of a formulation of calcium based compounds. This synthetic bone graft comes in the shape of granules or blocks. Bi-Ostetic™ is supplied sterile for single patient use only. Bi-Ostetic™ is biocompatible and resorbs in the human body as bone ingrowth occurs when applied according to its indications for use. The implant is bioresorbable and radio-opaque.

C. SUBSTANTIAL EQUIVALENCE INFORMATION

Bi-Ostetic™ is substantially equivalent to legally marketed, predicate devices Medtronic Mastergraft™ Resorbable Ceramic (K020986) and Interpore Cross International ProOsteon 500R (K990131). The products have identical indications-for-use, identical or very similar composition, and equivalent contraindications. They also have similar warnings, precautions and potential adverse events. The safety and effectiveness of Bi-Ostetic™ are adequately supported by the substantial equivalence information, materials data, and test results provided in the full document submitted within the scope of this Premarket Notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 3 0 2003

François Génin, Ph.D.
President and CEO
Berkeley Advanced Biomaterials, Inc.
1933 Davis Street Suite 307
San Leandro, California 94577

Re: K023703
Trade/Device Name: Bi-Ostetic™
Regulatory Class: Unclassified
Product Code: MQV
Dated: October 30, 2002
Received: November 4, 2002

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.

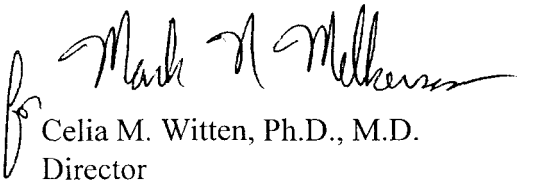
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K023703

Device Name: **Bi-Ostetic™ bone void filler**

Indications for Use:

Bi-Ostetic™ is an osteoconductive bone substitute shaped as granules or blocks (cancellous, cortical or cortico-cancellous) that are intended to be used to fill voids and gaps that are not intrinsic to the stability of the bone structure. These gaps or voids may be located in the extremities, spine, pelvis, or cranium.
The granules or blocks may be pressed into the void or into the surgical site by hand. The Bi-Ostetic™ granules or blocks provide void filling material that acts as a temporary support medium. The granules or blocks are not intended to provide structural support during the healing process. The implant is radio-opaque. Bi-Ostetic™ is biocompatible and resorbs in the body as bone ingrowth occurs.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K023703