Indications for Use

510(k) Number (if known):

Device Name: **Bi-Ostetic Foam**

Indications for Use:

Bi-Ostetic Foam is indicated for use in bony voids or gaps that are not intrinsic to the stability of the bony structure. The product should be gently packed into bony voids or gaps of the skeletal system (i.e., the extremities, spine and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced by the growth of new bone during the healing process. The bone graft can be mixed with autogenous bone marrow prior to use at the physician's discretion. In weight bearing situations, Bi-Ostetic Foam is to be used in conjunction with internal or external fixation devices. The fracture defect treated with Bi-Ostetic Foam should not exceed 30 mL.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Mulkey for MKM

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

H-Genin
Berkeley Advanced Biomaterials

MANUFACTURED AND DISTRIBUTED BY:
Berkeley Advanced Biomaterials
901 Grayson Street, Suite 101
Berkeley, CA 94710 USA
Phone: +1-510-883-0500
Fax: +1-510-883-0511
www.hydroxyapatite.com

STERILE R

INSTRUCTIONS FOR USE

IMPORTANT PRODUCT INFORMATION

ENGLISH

Please read before use

These instructions-for-use refer specifically to H-Genin

Materials and Device Description
H-Genin is a bone void filler consisting of demineralized bone matrix (DBM). The device provides a scaffold around which new bone can grow. This device is safe and has excellent biocompatibility. After it is implanted, it resorbs and is later replaced by natural bone. H-Genin is a natural choice for sparing patients the trauma of autograft harvesting.

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Donor Selection
All donor tissue is recovered, processed and distributed according to standards established by the American Association of Tissue Banks. Donor screening following the Tissue Banks International exclusion criteria is performed via donor physical inspection, interview with a person who knew the donor, review of available medical records, and a review of autopsy findings (when applicable). Individuals considered to be at high risk for AIDS or hepatitis as defined by the FDA and CDC are excluded from donorship. Using FDA licensed test kits in a CLIA certified lab, a serum sample from the donor has passed a hemodilution review and tested non-reactive for the following:
- Human immunodeficiency virus antibody (anti-HIV1 and 2)
- Human immunodeficiency virus (HIVp-24 and /or PCR) or (HIVp-24 and /or PCR and HIV 1 NAT) or (HIV 1 NAT)
- Hepatitis B surface antigen (HBsAg)
- Hepatitis B core antibody (HBcAb)
- Hepatitis C (anti-HCV) or (anti-HCV and HCV NAT)
- Human T-lymphotophic virus type I and II antibody (anti HTLV-I and II)
- Rapid plasma reagin (RPR) or serological tests for syphilis (STS).

Contraindications
This device is not designed or sold for any use except as indicated. Do not use the device in the presence of any contraindication. This device is contraindicated where the bone void filler is intended as structural support in the skeletal system (e.g. mandibular segment replacement). Other conditions representing relative contraindication include:
- severe vascular or neurological disease
- uncontrolled diabetes
- severe degenerative disease
- uncooperative patients who cannot or will not follow post-operative instruction, including individuals who abuse drugs and/or alcohol
- hypercalcemia, abnormal calcium metabolism
- existing acute or chronic infections, especially at the site of the operation
- inflammatory bone disease such as osteomyelitis
- malignant tumors
- severely impaired renal function.

Possible Adverse Reactions
An allograft may not elicit proper response from the recipient (e.g. fusion/union with adjacent tissue). It is possible for a host site to become infected. The allograft may not provide mechanical support and collapse, or may cause an inflammatory response. While efforts are made to ensure the safety of the tissue, current technologies may not preclude the transmission of disease, including hepatitis and HIV.

Reporting Adverse Reactions
The surgeon is responsible for reporting all adverse reactions potentially attributed to the allograft within 15 days of the occurrence. In such a case, contact Berkeley Advanced Biomaterials at +1.510.883.0500.

Warnings
Unused allograft, whole or partial, may not be repackaged, or sterilized a second time.
This allograft is intended for single patient use only.
While every effort has been made to ensure the quality of this allograft, Berkeley Advanced Biomaterials makes no claims concerning its biological or biomechanical properties. As with any allograft, despite strict screening/testing procedures, this allograft has the potential to transmit infectious agents to the recipient.
This allograft may contain trace amounts of processing agents such as iodine, ethanol, glycerol, or hydrogen peroxide.

Preoperative Procedure
In the incidence of an open fracture, initial debridement and wound management should be performed. Exercise care to minimize periosteal stripping. Infections must be treated and sepsis eradicated prior to the graft procedure. Use prophylactic antibiotic coverage as appropriate.

Surgical Procedure
All procedures should be performed in the operative room under aseptic conditions. Follow accepted procedures for grafting with fixation. Bone marrow is obtained by the standard bone marrow collection techniques, and the donor sites include iliac crest, fracture, or other sites. Exercise care not to collect blood. If marrow from the fracture site is used, it is important that the marrow has not been contaminated.

Storage Conditions
Store in a dry place at room temperature. Optimal Storage Conditions: 15-20°C (59-68°F), less than 50% relative humidity. DO NOT FREEZE.

Shelf Life and Disposal
The expiration date is printed on the label. DO NOT USE DEVICE AFTER THE EXPIRATION DATE.

Caution: U.S. Federal Law restricts this device to sale by or on the order of a physician or hospital.

Spec. No. 50347 Rev. A (Feb. 2007)

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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.