BIOMATLANTE

MAY - 3 2005

-Confidential-

MBCP™

510(k) Summary of Safety and Effectiveness

This 510(k) Summary for MBCP™ is provided as required per Section 513(1)(3) of the Food, Drug and Cosmetic Act.

1. GENERAL INFORMATION

Submitter's name and adress :	BIOMATLANTE ZA DES IV NATIONS 5, rue Edouard Belin -F- 44360 VIGNEUX DE BRETAGNE France
Contact :	Myriam VINCENT, Regulatory Affairs Manager Tel : +33 228 02 00 09 myriamvincent@biomatlante.com
FDA Establishment Number :	3002673655
Trade Name:	MBCP™
Common Name:	Resorbable Calcium Salt Bone Void Filler
Classification Name :	Resorbable Calcium Salt Bone Void Filler
Product Code :	MQV
CFR Section :	888.3045
Device Panel :	Orthopedic

Summary preparation date: April 12th, 2005

2. PREDICATE DEVICES

The subject device is substantially equivalent to similar previously cleared devices.

3. DEVICE DESCRIPTION

MBCP™ is a bone graft substitute. MBCP™ is a microporous and macroporous biphasic calcium phosphate ceramic consisting of 60% Hydroxyapatite (HA) and 40% beta-Tricalcium Phosphate (ß-TCP). MBCP™ is available in various shapes and sizes.
MBCP™ may be used with physiological saline, patient's own serum, whole blood, or bone marrow aspirate (BMA).
MBCP™ is provided sterile for single patient use.

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4. INTENDED USE

MBCP™ is intended for use as a bone void filler for bony voids or gaps of the skeletal system (e.g. extremities, spine and pelvis) that are not intrinsic to the stability of the bony structure. MBCP™ can be used with autograft as a bone graft extender. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone.
MBCP™ is a bone filler without initial mechanical properties. Therefore rigid fixation techniques may often be recommended.
When packed into a bony site, MBCP™ gradually resorbs and is replaced with bone during the healing process.

In addition, when used with appropriate opening osteotomy system devices, plates and screws, MBCP™ is intended to be used as a bone void filler in femoral or tibial osteotomies.
MBCP™ is to be used in association with adequate post-operative immobilization.

5. SUBSTANTIAL EQUIVALENCE INFORMATION

The intended use and material composition of MBCP™ Bone Graft Substitute is the same as previously cleared MBCP™ (K032268). MBCP™ Bone Graft Substitute and the predicate devices are substantially equivalent in design, materials of construction and function.

The safety and effectiveness of MBCP™ Bone Graft Substitute as modified in this submission is adequately supported by the substantial equivalence information, safety and performance data provided within this Premarket Notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 3 2005

Ms. Myriam VINCENT
Regulatory Affairs Manager
BIOMATLANTE
ZA DES IV NATIONS
5, rue Edouard Belin
-F-44360 VIGNEUX DE BRENTAGNE
France

Re: K043005
MBCP™
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler devices
Regulatory Class: Class II
Product Code: MQV
Dated: January 28, 2005
Received: February 2, 2005

Dear Ms. VINCENT:

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 (240) 276-0120. 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/industry/support/index.html.

Sincerely yours,

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K043005

Device Name: MBCP™

Indications For Use:

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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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K043005