

SEP 16 2005



-Confidential-

K051885

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 address :	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 :	Dental Bone Grafting Material Device
Product Code :	LYC
CFR Section :	21CFR part 872
Device Panel :	Oral/Dental

Summary preparation date:

September 12, 2005

2. PREDICATE DEVICES

The subject device is substantially equivalent to previously cleared devices.

3. DEVICE DESCRIPTION

MBCP™ is a Resorbable Bone Graft Substitute.

MBCP™ is a microporous and macroporous biphasic calcium phosphate ceramic consisting of Hydroxyapatite (HA) and beta-Tricalcium Phosphate (β -TCP).

MBCP™ presents a multidirectional interconnected porosity structure, similar to that of human cancellous bone.



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MBCP™ is presented in a porous form required for the biological exchanges particularly for bone ingrowth and mineralization.

The balance of a stable component (HA) and a more bioactive component (β -TCP) allied to the porosity involves the controlled process of ceramic resorption and bone substitution.

When packed into the bony site, MBCP™ gradually resorbs and is replaced with bone during the healing process.

4. INTENDED USE

MBCP™ is intended for use as a bone grafting material to fill, augment or reconstruct periodontal or oral/maxillofacial defects.

These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone.

MBCP™ can be used with autogenous bone grafting materials.

Typical uses include:

- Periodontal/Infrabony defects
- Ridge augmentation
- Extraction sites (implant preparation/placement)
- Sinus lifts
- Cystic cavities

5. SUBSTANTIAL EQUIVALENCE INFORMATION

The material composition of MBCP™ Resorbable Bone Graft Substitute for Dental Bone Grafting is the same as previously cleared MBCP™ (K032268, K043005).

Intended Use of MBCP™ Bone Graft Substitute is substantially equivalent to the predicates.

The safety and effectiveness of MBCP™ Resorbable Bone Graft Substitute for Dental Bone Grafting is adequately supported by the substantial equivalence information as well as biocompatibility testing, safety and performance data provided within this Premarket Notification.



SEP 16 2005

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Myriam Vincent
Regulatory Affairs Manager
Biomatlante
ZA LES IV Nations
5, Rue Edouard Berlin
F-44360 Vingneus de Bretagne
FRANCE

Re: K051885
Trade/Device Name: MBCP
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: II
Product Code: LYC
Dated: July 4, 2005
Received: July 12, 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) 276-0115. 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,



Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

K051885

Indications for Use

510(k) Number (if known):

Device Name: MBCP™

Indications for Use:

MBCP™ is intended for use as a bone grafting material to fill, augment or reconstruct periodontal or oral/maxillofacial defects.

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Over-The-Counter Use _____

Prescription Use X
Part 21 CFR 801 Subpart D)

AND/OR

(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)

Page 1 of _____

Susan Quares

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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