1 of 2

Biomatlante

K060732

JUN - 2 2006

-Confidential-

MBCP Gel™

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 Gel™
Common Name:	Dental Bone Graft
Classification Name :	Bone Grafting Material, Synthetic
Product Code :	LYC
CFR Section :	872.3930
Device Panel :	Dental

Summary preparation date: March 6th, 2006.

2. PREDICATE DEVICES

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

3. DEVICE DESCRIPTION

MBCP Gel™ is a Resorbable Bone Graft Substitute that is rapidly replaced by newly-formed bone. This material is a non self setting gel providing mechanical resistance after healing and osseous rehabilitation.
MBCP Gel™ is composed of biphasic Calcium Phosphate (60% Hydroxyapatite (HA) and 40% beta-Tricalcium Phosphate (β-TCP)) particles associated with an excipient vehicle of pharmaceutical grade quality (hydroxypropylmethylcellulose in an aqueous solution). The soluble

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carrier acts as a spacer and a binder of the particles. MBCP Gel™ provides an environment for bone ingrowth. On time MBCP Gel™ is fully resorbable.

MBCP Gel™ is provided sterile for single patient use in a syringe.

4. INTENDED USE

MBCP Gel™ is intended for use as a bone grafting material to fill, augment or reconstruct osseous bone defects in particular in periodontal or oral/maxillofacial applications.
These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone.
MBCP Gel™ can generally be used for bone filling in closed cavities.
MBCP Gel™ can be used with autogenous bone grafting materials.

Typical uses include but are not limited to:

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

5. SUBSTANTIAL EQUIVALENCE INFORMATION

The principal component and intended use of MBCP Gel™ is the same as previously cleared MBCP™ (K051885). MBCP Gel™ and the predicate devices are substantially equivalent in design, materials of construction and function.

The safety and effectiveness of MBCP Gel™ as a modification to MBCP™ presented 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

JUN - 2 2006

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

Re: K060732
Trade/Device Name: MBCP Gel™
Regulation Number: 872.3930
Regulation Name: Bone Grafting Material Synthetic
Regulatory Class: II
Product Code: LYC
Dated: March 6, 2006
Received: March 20, 2006

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.

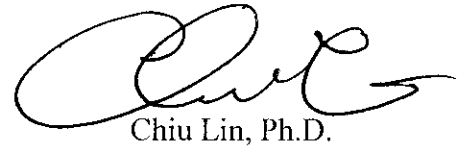
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

K060732

Indications for Use

510(k) Number (if known):

Device Name: MBCP Gel™

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)

...ion Sign-Off)
...n of Anesthesiology, General Hospital,
...tion Control, Dental Devices

...(k) Number: K060732