K093122

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MAR 15 2010

Biomatlante

Bone Grafting Material

Summary of Safety and effectiveness

A. Submitter's Name and adress

BIOMATLANTE
ZA DES IV NATIONS
5, rue Edouard Belin
-F- 44360 VIGNEUX DE BRETAGNE
Phone: 0033 228 020 009
Fax: 0033 228 020 010

Contact: Jeanne CHAMOUSSET-ROMAN
Regulatory Affairs Manager

Summary preparation date: September 24th, 2009

B. Official Contact Person

RACQUEL Z LEGEROS, PHD

NEW YORK UNIV COLLEGE OF DENTISTRY
345 east 24th street
rm 806
New York, NY 10010

Phone: 212 998
Fax: 212 995
Email: rzl1@nyu.edu

C. Establishment registration number : 3002673655

D. Device name

Bone Grafting Material

E. Trade Name

MBCP+

K093122

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Summary of Safety and effectiveness

F. Device Classification Name

Bone Grafting Material (21 CFR 872.3930)

G. Proposed regulatory Class

Class II

H. Device Product Code

LYC

I. Panel Code

Dental

J. Legally marketed devices to which Biomatlante claims equivalence (Predicate devices)

Product	Applicant	Class	510(k) number
OsSatura™ Dental	Isotis Orthobiologics, Inc.	II	K042706
Cerasorb™ Dental	Curasan AG	II	K051443
MBCP™	Biomatlante	II	K051885

K. Device Description

MBCP+™ is a bone graft material used in dental applications. The MBCP+™ product consists of a biphasic ceramic (e.g hydroxyapatite and tricalcium phosphate beta). MBCP+™ dental product is a synthetic device, available in different sizes of granules. MBCP+™ product is available sterile for single use.

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L. Intended use:

MBCP+™ is intended for use as a bone grafting material to fill, augment or reconstruct periodontal or bony defects of the oral and maxillofacial region.
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

M. Summary of the technical characteristics

The bone substitutes concerns by this premarket notification submission and the predicate devices above mentioned have the same intended use, the same principle of operation and very similar technological characteristics. They are sterile devices made of calcium salt. MBCP+™ and predicates are provided sterile for single-use.

N. Non clinical performance data

Testing, performed according to the Guidance Class II Special Controls Guidance Document: Dental Bone Grafting Material Devices; Guidance for Industry and FDA Staff issued April 28 2005, support the substantial equivalence between MBCP+ and the predicate device.

O. Conclusion

MBCP+™ is claimed to be substantially equivalent in term of safety and effectiveness to the predicate devices as a resorbable bone grafting material.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAR 15 2010

Ms. Jeanne Chamousset-Roman
Regulatory Affairs Manager
Biomatlante
5 Rue Edouard Belin Za Les Quatre Nations
Vigneux De Bretagne
FRANCE 44360

Re: K093122
Trade/Device Name: MBCP+™
Regulation Number: 21CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: II
Product Code: LYC
Dated: March 2, 2010
Received: March 4, 2010

Dear Ms. Roman:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K093122

Biomatlante

Bone Grafting Material

Indications for Use

510(k) Number (if known): _K093122

Device Name: **MBCP+™**

Indications for Use:

MBCP+™ is intended for use as a bone grafting material to fill, augment or reconstruct periodontal or bony defects of the oral and maxillofacial region.
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

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

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

510(k) Number: K093122