K063527

Biomatlante

MBCP+ ™

510(k) Summary

JUL 30 2007

BIOMATLANTE
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Contact: Adeline Filliâtre
Regulatory Affairs Manager

This summary was prepared on July 2007, 16th

1. DEVICE IDENTIFICATION

Trade Name:	MBCP+™
Common Name:	Resorbable bone substitute
Classification Name :	Resorbable calcium salt bone void filler device
Product Code :	MQV
Regulatory Status :	Class II
CFR Section :	888.3045

2. PREDICATE DEVICES

Product Code	Manufacturer	510(k) #	Product
MQV	Orthotec	K040514	**EOVIA**
MQV	Howmedica Osteonics	K033258	**BONESAVE**

3. DEVICE DESCRIPTION

MBCP+™ is a non structural bone graft substitute, which is resorbable and able to be replaced by newly-formed bone. The MBCP+™ is a ceramic constituted of two-phase of calcium phosphate 20 % hydroxyapatite and 80 % tricalcium phosphate beta. MBCP+™ is presented in a porous form.

There are two types of porosity in MBCP+™:

The microporosity (pores smaller than 5µm) is constituted by all the spaces between the ceramic. The microporosity allows the biological fluids to circulate.
The macroporosity (pores diameters bigger than 100µm) provides a porous scaffold upon which bone formation can occur at the expense of the ceramic.

4. INTENDED USE

MBCP^{+TM} is intended for use as 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. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone.
MBCP+^{TM} is provided sterile for single patient use.

5. SUBSTANTIAL EQUIVALENCE INFORMATION

Documentation was provided which demonstrated the MBCP^{+TM} to be substantially equivalent to previously cleared devices. The substantial equivalence is based upon equivalence in indications for use, anatomic sites, design, material and function.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 30 2007

Biomatlante
% Ms. Adeline Filliatre
Regulatory Affairs Manager
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5, rue Edouard Belin
Vigneux de Brentagne
France 44360

Re: K063527
Trade/Device Name: MBCP+
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: May 28, 2007
Received: June 7, 2007

Dear Ms. Filliatre:

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.

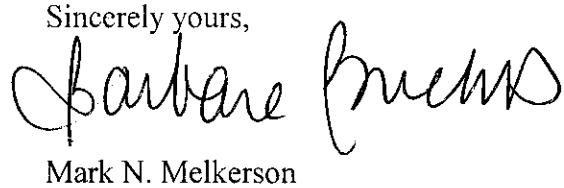
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

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 toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Biomatlante

MBCP+™

Indications for Use

510(k) Number (if known): _K063527___

Device Name: MBCP+ ™

Indications for Use:

MBCP+ ™ is intended for use as 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. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone.
MBCP+™ is provided sterile for single patient use.

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)

Laurie Gruen

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

510(k) Number K063527