K083858

1 of 2

510(k) Summary

Augma Biomaterials, Ltd.
Bond Bone™

ADMINISTRATIVE INFORMATION

MAR 1 7 2009

Manufacturer Name:	Augma Biomaterials, Ltd. 8 Usishkin Street Netanya 42273 Israel Telephone: +972-(0)77-3253128 Fax: +972-(0)9-8335281
Official Contact:	Dr. Amos Yahav
Representative/Consultant:	David J. Collette or Floyd G. Larson PaxMed International, LLC 11234 El Camino Real, Suite 200 San Diego, CA 92130 Telephone: +1 (858) 792-1235 Fax: +1 (858) 792-1236 email: dcollette@paxmed.com flarson@paxmed.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	Bond Bone™
Common Name:	Bone Grafting Material, Synthetic
Classification Regulations:	21 CFR 872.3930
Product Code	LYC
Classification Panel:	Dental Products Panel
Reviewing Branch:	Dental Devices Branch

INTENDED USE

Bond Bone™ is indicated for use in the following ways: by itself in bone regenerative techniques, mixed with other suitable bone filling agents to prevent particle migration in an osseous defect, and to provide a resorbable barrier over other bone graft material.

K083858

2 of 2

DEVICE DESCRIPTION

Bond Bone™ is a synthetic osteoconductive, bioresorbable bone grafting material composed of biphasic calcium sulfate in granulated powder form, intended to fill, augment, or reconstruct periodontal or bony defects of the oral and maxillofacial region. When mixed with saline, Bond Bone forms a paste and hardens via a cementitious reaction. The product is provided sterile and for single patient use.

EQUIVALENCE TO MARKETED PRODUCT

Augma Biomaterials, Ltd., demonstrated that, for the purposes of FDA's regulation of medical devices, Bond Bone is substantially equivalent in indications and design principles to predicate devices, each of which has been determined by FDA to be substantially equivalent to preamendment devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 2 2009

Augma Biomaterials, Limited
C/o Mr. David J. Collette
PaxMed International, LLC
11234 El Camino Real, Suite 200
San Diego, California 92130

Re: K083858
Trade/Device Name: Bond Bone™
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: II
Product Code: LYC
Dated: December 23, 2008
Received: December 29, 2008

Dear Mr. Collette:

This letter corrects our substantially equivalent letter of March 12, 2009.

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 (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.

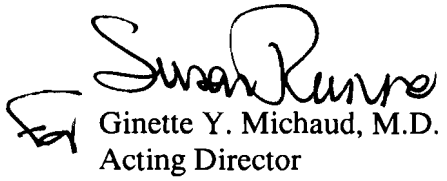
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 continue 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) 276-0101. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Ginette Y. Michaud, M.D.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Bond Bone™

Indications for Use:

Bond Bone™ is indicated for use in the following ways: by itself in bone regenerative techniques, mixed with other suitable bone filling agents to prevent particle migration in an osseous defect, and to provide a resorbable barrier over other bone graft material.

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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K083858