510(k) Summary
Augma Biomaterials, Ltd.
Bond Apatite™
K121177

DEC 05 2013

December 5, 2013

ADMINISTRATIVE INFORMATION

Manufacturer Name	Augma Biomaterials, Ltd. Usishkin 8 Netanya, Israel 42273 Telephone: +972-(0)77-559-1945 Fax: +972-(0)4-627-5337
Official Contact	Dr. Amos Yahav, DMD
Representative/Consultant	Kevin A. Thomas, PhD Linda K. Schulz, BSDH, RDH PaxMed International, LLC 11234 El Camino Real, Suite 200 San Diego, CA 92130 Telephone: +1 (858) 792-1235 Fax: +1 (858) 792-1236 Email: kthomas@paxmed.com lschulz@paxmed.com

DEVICE NAME AND CLASSIFICATION

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

INTENDED USE

Bond Apatite™ is a synthetic osteoconductive, bioresorbable bone grafting material composed of hydroxyapatite and biphasic calcium sulfate in granulated powder form, intended to fill, augment, or reconstruct periodontal or bony defects of the oral and maxillofacial region.

DEVICE DESCRIPTION

Bond Apatite is composed of hydroxyapatite and biphasic calcium sulfate in granulated powder form. The hydroxyapatite component is sintered hydroxyapatite granules that conform to ISO 13779-1 *Implants for surgery – Hydroxyapatite – Part 1: Ceramic Hydroxyapatite* and ISO 13779-3 *Implants for surgery – Hydroxyapatite – Part 3: Chemical analysis and characterization of crystallinity and phase purity.* The calcium sulfate material is Bond Bone™, a mixture of surgical grade calcium sulfate dihydrate and calcium sulfate hemihydrate, and cleared under K083858. The calcium sulfate component conforms to the chemical requirements of ASTM F2224 *Standard Specification for High Purity Calcium Sulfate Hemihydrate or Dihydrate for Surgical Implants.* Bone Apatite is provided sterile, in a single unit size of 1 cc in a disposable applicator that is used for mixing the dry powder with sterile saline and for delivery to the treatment site.

EQUIVALENCE TO MARKETED DEVICE

Augma Biomaterials, Ltd., demonstrated that, for the purposes of FDA's regulation of medical devices Bond Apatite is substantially equivalent in indications and design principles to the following legally marketed predicate devices:

Augma Biomaterials, Ltd., Bond Bone™, K083858;

BONESUPPORT AB, CERAMENT™|BONE VOID FILLER (A0210-12), K090871; and

Lifecore Biomedical, Inc., HAPSET Hydroxylapatite Bone Graft Plaster, K910432.

The intended use, materials, design, and functional characteristics of Bond Apatite and the predicate devices are substantially the same. The subject device and the predicate device Bond Bone are indicated for use in dental bone regeneration procedures. The intended use of the subject device and both predicate devices is to fill bony defects. The calcium sulfate material in the subject device Bond Apatite is the predicate device, Bond Bone, cleared under K083858. By weight, Bone Apatite is approximately 38.6% hydroxyapatite and 61.4% biphasic calcium sulfate. The predicate devices CERAMENT™|BONE VOID FILLER and HAPSET Hydroxylapatite Bone Graft Plaster consist of powdered hydroxyapatite and calcium sulfate hemihydrate.The subject device and the predicate devices are supplied as a dry powder to be mixed with saline or other liquid to form a putty before use, and all are provided sterile in a single unit mixing/delivery applicator (syringe) for single patient use.

Any differences in the technological characteristics between the subject and predicate devices do not raise new issues of safety or efficacy.

Data submitted, referenced, or relied upon to demonstrate substantial equivalence included: material characterization by Fourier transform infrared spectroscopy, x-ray diffraction, and inductively coupled plasma optical emission spectrometry; physical characterization by gravimetric methods, mechanical sieve separation, scanning electron microscopy; performance characteristics including setting time and reaction temperature measurements, compressive mechanical properties, pH, dissolution, device handling under simulated usage conditions, and clinical performance testing.

The data included in this submission demonstrates substantial equivalence to the predicate devices listed above.

Overall, Bond Apatite™ has the following similarities to the predicate devices:

- has the same intended use,
- uses the same operating principle,
- incorporates the same basic design,
- incorporates the same or very similar materials, and
- has similar packaging and is sterilized using the same materials and processes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

December 5, 2013

Augma Biomaterials, Limited
C/O Kevin A. Thomas, PhD.
PaxMed International, LLC
11234 El Camino Real, Suite 200
San Diego, CA 92130

Re: K121177
Trade/Device Name: Bond Apatite™
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: II
Product Code: LYC
Dated: November 26, 2013
Received: December 2, 2013

Dear Dr. Thomas:

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 contact 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. 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,

Kwame O. for
Ulmer -S

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K121177

Indications for Use

510(k) Number: _____

Device Name: Bond Apatite™

Indications for Use:

Bond Apatite™ is a synthetic osteoconductive, bioresorbable bone grafting material composed of hydroxyapatite and biphasic calcium sulfate in granulated powder form, intended to fill, augment, or reconstruct periodontal or bony defects of the oral and maxillofacial region.

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)

Susan Runner DDS, MA

Mary S. Runner -S
2013.12.05
14:40:01 -05'00'