K090950

JUL - 2 2010

# 510(K) Summary

Submitter
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Device Information

Trade name: Bone Plus™ BCP

Common name: Bone grafting material

Classification name: Bone Grafting Material, Synthetic

Classification product code: LYC

Regulation number: 872.3930

Device class: Class II

Device Description

Bone Plus™ BCP is a synthetic resorbable osteo-conductive bone graft substitute composed of Hydroxyapatite (HA) and beta-Tricalcium Phosphate (beta-TCP). Bone Plus™ BCP presents a interconnected porosity structure, similar to that of human cancellous bone. It is supplied sterile and it is dedicated for single use.

Indication for Use

Bone Plus™ BCP is intended to fill, augment, or reconstruct periodontal or bony defects of the oral and maxillofacial region.

- Augmentation or reconstructive treatment of alveolar ridge
- Filling of periodontal defects
- Filling of defects after root resection, apicocectomy, and cystectomy
- Filling of extraction sockets to enhance preservation of the alveolar ridge
- Elevation of maxillary sinus floor

- Filling of periodontal defects in conjunction with products intended for Guided Tissue Regeneration (GTR) and Guided Bone Regeneration (GBR)
- Filling of peri-implant defects in conjunction with products intended for Guided Bone Regeneration

Device Type

- Bone Plus™ BCP Needle Graft.

Materials

Bone Plus™ BCP is comprised of 60% Hydroxyapatite (HA) and 40% Beta Tricalcium Phosphate (β-TCP)

Predicate Devices

The subject device is substantially equivalent to the following predicate devices:

- MBCP™ (K051885) manufactured by Biomatlante Co., Ltd.
- Cerasorb® Dental (K051443) manufactured by Curasan AG
- Bio-Oss Collagen (K974399) manufactured by Geistlich-Pharma

Comparison to Predicate Devices

Testing and other comparisons have established that the subject of Bone Plus™ BCP substantially equivalent in design, materials, indications and intended use, and performance to other predicate devices of the type currently marketed in the U.S.

- Histomorphometric Evaluation of Bone Plus™ BCP
- Chemical and Physical Analysis of Bone Plus™ BCP
- Porosity assessment of Bone Plus™ BCP
- Solubility Test of Bone Plus™ BCP
- Clinical Study of Bone Plus™ BCP

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

Megagen Implant Company, Limited
C/O Ms. Joyce Bang
Kodent, Incorporated
13340 East Firestone Boulevard, Suite J
Santa Fe Springs California 90670

JUL - 2 2010

Re: K090950
Trade/Device Name: Bone Plus BCP
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: II
Product Code: LYC
Dated: June 20, 2010
Received: June 22, 2010

Dear Ms. Bang:

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

## Indication for Use

**510(K) Number (if known): K090950**

**Device Name:** Bone Plus™ BCP

**Indication for Use:**

Bone Plus™ BCP is intended to fill, augment, or reconstruct periodontal or bony defects of the oral and maxillofacial region.

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- Filling of peri-implant defects in conjunction with products intended for Guided Bone Regeneration

Prescription Use _____x_____ AND/OR Over-The-Counter _____

(Part 21 CFR 801 Subpart D) (Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Ken Mulley for MSR

Division Sign-Off)
ivision of Anesthesiology, General Hospital
irection Control, Dental Devices

10(k) Number: K090950