K122240

510(K) Summary

AUG 2 1 2012

Submitter
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Official Correspondent/ US agent
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KoDent, Inc.
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Device Information

Trade name: Bone Plus ™ BCP Eagle Eye

Common name: Bone grafting material

Classification name: Bone Grafting Material, Synthetic

Classification product code: LYC

Regulation number: 872.3930

Device class: Class II

Date prepared: 7/13/2012

Device Description

Bone Plus™ BCP Eagle Eye is an osteocondective, synthetic bone graft material. Bone Plus™ BCP Eagle Eye is biphasic calcium phosphate (BCP) bioceramics that is composed of bioactive HA and bioresorbable beta-TCP. The ratio of HA to beta-TCP is 60:40. Bone Plus has interconnected porous structure that is made of macro-pores and/or micro-pores. Bone Plus™ BCP Eagle Eye is supplied in granules of different sizes and shapes.

Device Type

- Bone Plus™ BCP Eagle Eye

Indication for Use

Bone Plus ™ BCP Eagle Eye 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

Materials

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

Non Clinical Test Report

Ca/P Ratio, Crystallinity was performed according to ISO 13779-1 and ISO 13779-3 Standard.

Phase Analysis and Phase purity was performed according to ISO 13779-3 Standard.

Porosity was performed according to ISO 13779-3 Standard.

pH and water solubility Analysis was performed according to ISO 10993-14 Standard.

Implantation test was performed according to ISO 10993-6 Standard.

Predicate Devices

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

- Bone PlusTM BCP (K090950) manufactured by Megagen Implant Co., Ltd.

Comparison to Predicate Devices

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

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., LTD
C/O Ms. April Lee
Kodent, Incorporated
325 N. Puente St. Unit B
Brea, California 92821

AUG 2 1 2012

Re: K122240
Trade/Device Name: Bone Plus™ BCP Eagle eye
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: II
Product Code: LYC
Dated: July 26, 2012
Received: July 27, 2012

Dear Ms. Lee:

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): K122240

Device Name: Bone Plus™ BCP Eagle Eye

Indication for Use:

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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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

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

510(k) Number: K122240