K113246

510(k) Summary

[as required by 807.92(c)]

JAN 16 2013

Sponsor/Applicant

NIBEC Co., Ltd.

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Iwol-myeon, Jincheon-gun, Chungcheongbuk-do, Korea

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Contact : Dr. Park, Yoon-Jeong

Date Prepared : JANUARY 07, 2013

Device Name and Identification

Proprietary Name : OCS-B™

Common / Usual Name : Bone Mineral Matrix

Anorganic Bovine Bone Grafting Material

Classification Name : Bone Grafting Material

Animal Source Dental Bone Grafting Material

Predicate Device

Bio-Oss® bone grafting material (K871773, K952617, K970321, K033815)

Manufactured by :

Geistlich Pharma AG

Bahnhofstrasse 40

CH-6110 Wolhusen

Switzerland

Device Category/Class

Device Class : Class II

Regulation Number : 21 C.F.R. 872.3930

Product Code : NPM

Indication for use

OCS-B™ cancellous and cortical granules are recommended for:

- Augmentation or reconstructive treatment of the alveolar ridge.
- Filling of infrabony periodontal defects.
- Filling of defects after root resection, apicoectomy, 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 (GBR)

Device Description

OCS-B™ is a sterile, porous bone mineral matrix produced by the removal of organic compounds from bovine bone. It is supplied as cancellous (spongiosa) or cortical granules in a single use container, packaged in a secondary thermoform blister, and sterilized by γ-irradiation.

Basis for Substantial Equivalence

OCS-B™ and Bio-Oss® have a similar physical and chemical structure. Both are porous, biocompatible bone grafts that facilitate the formation and mineralization of new bone by the

osteoblast. As both products have same source of bone (bovine source) and similar process for removal of organic compounds, the product is substantially equivalent to Bio-Oss®.

The following table summarizes the basis for the Sponsor's substantial equivalence determination :

Table 1 Substantial Equivalence Comparison

ITEM	OCS-B™	Bio-Oss®
Intended Use	Used as an adjective therapy in restoring bony defects	Used as an adjective therapy in restoring bony defects
Target population	Human Oral, Periodontal	Human Oral, Periodontal
Dosage form	Granules contained in single use container	Granules contained in single use container
Granule sizes	0.2mm to 1.0mm or 1.0mm to 2.0 mm granules	0.25mm to 1.0mm or 1.0mm to 2.0 mm granules
Material	Anorganic derived osteoconductive hydroxyapatite bone mineral	Anorganic derived osteoconductive hydroxyapatite bone mineral
Source bone	Bovine bone	Bovine bone
Physical Morphology	Trabecular, interconnecting macro and micro pores	Trabecular, interconnecting macro and micro pores
Biocompatibility	Biocompatible, as demonstrated by : - Genotoxicity testing *(In vitro, In vivo)* - Intracutaneous reactivity testing - Maximization and sensitization testing - Pyrogen testing - Acute systemic toxicity testing - Cytotoxicity testing - Implantation testing - Preclinical safety and efficacy testing - Clinical case studies	Biocompatible (as demonstrated in published literature)

Performance	Bone formation	Bone formation
Compatibility w/other devices	Can be used with GTR membrane	Can be used with GTR membrane
Sterilization Process	Sterile by Gamma irradiation	Sterile by Gamma irradiation
Chemical Composition	Similar to Bio-Oss® based on chemical analysis, XRD, FT-IR and ICP analysis	Similar to OCS-B™ based on chemical analysis, XRD, FT-IR and ICP analysis
Anatomical sites	Oral, Periodontal	Oral, Periodontal
Non-pyrogenic	Yes	Yes
Shelf life	3 years	Determined by Manufacturer
Risk	Non-risk, as demonstrated by : - TSE inactivation Process Validation - Virus Clearance study - Analysis of residual solvent - Risk analysis - Cleaning Validation	-

Brief Summary of Data Submitted

The Sponsor evaluated the performance characteristics of OCS-B™ and Bio-Oss® with a thorough chemical and physical characterization. The physical and chemical characteristics of the products were found to be comparable. Further, in several animal studies, both products were found to grow new bone and be subsequently resorbed at similar rates. Finally, in a clinical case series, use of OCS-B™ resulted in defect healing and formation of new bone of sufficient quality to obtain dental implant placement. The submission includes a summary of seven individual case studies of OCS-B™. The patients were treated for intra-bony periodontal defects. For each case study, the report includes baseline radiographs, radiographs at various time point, and core biopsy for histological evaluation. Histological and radiographic images demonstrate new bone growth.

OCS-B™ was the subject of the full range of biocompatibility tests recommended in the FDA's "Class II. Special Controls Guidance Document : Dental Bone Grafting Devices" and in accordance with ISO 10993. Organic material has been removed from the product, and product specifications have been established to limit protein content. Throughout the risk analysis for each production step, for example, cleaning validation, the removal of organic solvent, the risk control was conducted during the manufacturing process. In addition, the

TSE inactivation validation as well as virus inactivation study result was conducted. Further, the product is sterilized to achieve a sterility assurance level SAL 1×10^{-6}.

Based on the information presented herein, it has been demonstrated that OCS-B™ is substantially equivalent to Bio-Oss®.

Conclusion

The OCS-B™ presents the same types of potential risks to consumers as the predicate device Bio-Oss®, and has controlled these risks in a similar manner. And biocompatibility tests and compatibility test show that the device meets the requirements of those standards. Literatures and post market experience show that the device is substantially equivalent. Comparison with the predicate device shows that the device has similar specification and performance.

Therefore, it is concluded that OCS-B™ are substantially equivalent to the predicate device.

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

January 16, 2013

Nibec Company, Limited
C/O Mr. Daniel Nam
General Manager
Pats Corporation
4568 West 1st Street, Suite 104
LOS ANGELES CA 90004

Re: K113246
Trade/Device Name: OCS-B™
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: II
Product Code: NPM
Dated: January 7, 2013
Received: January 14, 2013

Dear Mr. Nam:

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,

Kwame O. Ulmer

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K113246

Device Name: OCS-B™

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____ (Part 21 CFR 801 Subpart D) (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 2013.01.15 15:02:04 -05'00'

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

510(k) Number: K113246