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

June 5, 2015

Chiyewon
c/o Mr. Daniel Nam
Pats Corp
4568 W. 1st St. Suite 104
Los Angeles, California 90004

Re: K140021
Trade/Device Name: Ti-oss®
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: II
Product Code: NPM
Dated: May 4, 2015
Received: May 5, 2015

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 contact the Division of Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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 Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory, Infection
Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*

K140021

Device Name

Ti-oss®

Indications for Use *(Describe)*

Ti-oss® is intended for use in dental surgery.
The product is recommended for the following surgeries :
* Augmentation or reconstructive treatment of alveolar ridge
* Filling of 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

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(k) Summary

[as required by 807.92(c)]

1. Applicant

CHIYEWON Co., Ltd.
6F., 192, Gyeongchun-ro, Guri-si, Gyeonggi-do, Republic of Korea
Phone : 82-31-568-1809
Fax : 82-31-553-3612
Contact : Kim, Sung-O

2. Date Prepared : June 4, 2014

3. Device Name and Identification

Proprietary Name : Ti-oss®
Device Class : Class II
Regulation Number :21 C.F.R. 872.3930
Product Code : NPM
Common / Usual Name : Animal Source Dental Bone Grafting Material
Classification Name : Bone Grafting Material

4. Predicate Device

SE Number: K113246
Product name: OCS-B™
Company: NIBEC Co., Ltd.

5. Indication for use

Intended for use in dental surgery.
The product is recommended for the following surgeries:
- Augmentation or reconstructive treatment of alveolar ridge
- Filling of 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

6. Device Description

Ti-oss® 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.

Name as per Device Label	Model No.	Brief Description of Item
Ti-oss®, 0.25g, 0.2-1.0mm	25-0210	0.25g, 0.2-1.0mm particle size, granules in the vial
Ti-oss®, 0.5g, 0.2-1.0mm	05-0210	0.5g, 0.2-1.0mm particle size, granules in the vial
Ti-oss®, 1g, 0.2-1.0mm	10-0210	1g, 0.2-1.0mm particle size, granules in the vial
Ti-oss®, 2g, 0.2-1.0mm	20-0210	2g, 0.2-1.0mm particle size, granules in the vial
Ti-oss®, 0.1g, 0.5-1.2mm	01-0512	0.1g, 0.5-1.2 mm particle size, granules in the vial
Ti-oss®, 0.25g, 0.5-1.2mm	25-0512	0.25g, 0.5-1.2mm particle size, granules in the vial
Ti-oss®, 0.5g, 0.5-1.2mm	05-0512	0.5g, 0.5-1.2mm particle size, granules in the vial
Ti-oss®, 1g, 0.5-1.2mm	10-0512	1g, 0.5-1.2mm particle size, granules in the vial
Ti-oss®, 2g, 0.5-1.2mm	20-0512	2g, 0.5-1.2mm particle size, granules in the vial
Ti-oss®, 0.1g, 1.2-1.7mm	01-1217	0.1g, 1.2-1.7mm particle size, granules in the vial
Ti-oss®, 0.25g, 1.2-1.7mm	25-1217	0.25g, 1.2-1.7mm particle size, granules in the vial

Ti-oss®, 0.5g, 1.2-1.7mm	05-1217	0.5g, 1.2-1.7mm particle size, granules in the vial
Ti-oss®, 1g, 1.2-1.7mm	10-1217	1g, 1.2-1.7mm particle size, granules in the vial
Ti-oss®, 2g, 1.2-1.7mm	20-1217	2g, 1.2-1.7mm particle size, granules in the vial
Ti-oss® Syringe, 0.25g, 0.5-1.2mm	S25-0512	0.25g, 0.5-1.2mm particle size, granules in the Syringe applicator
Ti-oss® Syringe, 0.5g, 0.5-1.2mm	S05-0512	0.5g, 0.5-1.2mm particle size, , granules in Syringe applicator
Ti-oss® Syringe, 0.25g, 1.2-1.7mm	S25-1217	0.25g, 1.2-1.7mm particle size, granules in the Syringe applicator
Ti-oss® Syringe, 0.5g, 1.2-1.7mm	S05-1217	0.5g, 1.2-1.7mm particle size, granules in the Syringe applicator

7. Basis for Substantial Equivalence

Ti-oss® and OCS-B™ 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 OCS-B™

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

Substantial Equivalence Comparison

ITEM	Ti-oss®	OCS-B™
Intended Use	Intended for use in dental surgery. The product is recommended for the following surgeries: - Augmentation or reconstructive treatment of alveolar ridge - Filling of periodontal defects - Filling of defects after root resection, apicoectomy, and cystectomy - Filling of extraction sockets to	OCS-B™ cancellous and cortical granules are recommended for: - Augmentation or reconstructive treatment of alveolar ridge - Filling of infrabony periodontal defects. - Filling of defects after root resection, apicocectomy, and cystectomy

	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	- 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
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, 0.5mm to 1.2mm, 1.2mm to 1.7mm	0.2mm 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	☐ Appearance Test ☐ Packaging test ☐ Packaging (Dye infiltration test) ☐ Demension (Particle size Test) ☐ Weight Test ☐ Ca/P ratio ☐ Crystallinity ☐ Heavy metal ☐ Porosity ☐ Solubility ☐ Extraction ☐ Sterility	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 predicate based on chemical analysis, XRD, FT-IR and ICP analysis	Similar to based on chemical analysis, XRD, FT-IR and ICP analysis
Anatomical sites	Oral, Periodontal	Oral, Periodontal
Non-pyrogenic	Yes	Yes
Shelf life	2 years	Determined by Manufacturer
Risk	Non-risk, as demonstrated by : - Virus Clearance study - Analysis of residual solvent - Risk analysis - Cleaning Validation	-

Brief Summary of Data Submitted

The Sponsor evaluated the performance characteristics of Ti-oss® and OCS-B™ with a thorough chemical and physical characterization. The physical and chemical characteristics of the products were found to be comparable as shown in the following:

- Appearance Test by visual inspection
- Particle Size test by ISO 3310-1 and particle size distribution
- Porosity, Pore size distribution, and level of interconnectivity
- Weight Test by gravimetric
- Structure comparison by SEM
- FT-IR Analysis by USP 29
- ICP Analysis by ISO 11885
- XRD Analysis
- Loss on drying test
- pH test by USP 29
- KMnO4 Volume for Reduction Test
- UV(Ultraviolet) Absorbance Analysis
- Heavy metal test by USP 29
- Residue on Ignition Test
- Pyrogenicity LAL testing
- Sterility test by USP 29

In a clinical case series, use of Ti-oss® resulted in defect healing and formation of new bone of sufficient quality to obtain dental implant placement. 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 and shown in the table as below.

Case	Subject	Location	Bone defect type
Case 1	61-Y-O-Female	Left Maxillary First, Second Molar area (operation site : #26,27)	Insufficient alveolar ridge height due to significant bone resorption vertically and laterally
Case 2	58-Y-O-Female	Right Maxillary First Molar area (operation site : #16)	Insufficient alveolar ridge height due to pneumatization and bone resorption
Case 3	53-Y-O-Male	Right Maxillary First Molar area (operation site : #16)	Big extraction defect with vertical alveolar bone resorption and insufficient alveolar ridge height
Case 4	47-Y-O-Female	Right Maxillary First Molar area (operation site : #16)	Significant vertical and lateral bone resorption with no buccal and lingual wall
Case 5	57-Y-O-Female	Left Mandibular central incisor area (operation site : #31)	Significant bone loss on the lingual side of central incisor
Case 6	47-Y-O-Male	Left Mandibular Second Molar defect (operation site : #37)	Big extraction defect caused by advance periodontal disease

Ti-oss® granules and the application syringe were 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. A viral inactivation study was conducted for BHV, BVDV, BPIV, and CPV viri. Further, the product is sterilized to achieve a sterility assurance level

SAL 1 x 10^{-6}. Finally, accelerated and real-time shelf life testing was conducted according to ASTM F88, ASTM F1140, ASTM F2096, ASTM F1929, and ASTM F1608.

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

Conclusion

The Ti-oss® presents the same types of potential risks to consumers as the predicate device OCS-B™, 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, in vitro chemical and physical characterization tests, and clinical data 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 Ti-oss® is substantially equivalent to the predicate device.