DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Datum Dental Ltd
% Janice Hogan
Partner
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October 16, 2017

Re: K163714
Trade/Device Name: Ossix Bone
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: Class II
Product Code: NPM
Dated: July 5, 2017
Received: July 5, 2017

Dear Janice Hogan:

This letter corrects our substantially equivalent letter, indications for use and the correct 510(k) Summary of July 18, 2017.

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 Parts 801 and 809); 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 Parts 801 and 809), 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" (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 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,

Mary S. Runner -S

for
Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
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)*

K163714

Device Name

OSSIX™ BONE

Indications for Use *(Describe)*

OSSIX™ BONE is intended for the following uses:

- Augmentation or reconstructive treatment of the 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 the 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).

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)*

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datumdental

510(k) Summary

I. Submitter

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Contact person: Arie Goldlust, CEO, VP R&D

Date prepared: July 5, 2017

II. Device

Trade name: OSSIX™ BONE
Common name: Dental bone grafting material
Classification name: Bone grafting material (21 CFR 872.3930)
Regulatory class: II
Product code: NPM

III. Predicate Device

Primary predicate: Geistlich Bio-Oss Collagen® (K122894)

References devices: OSSIX® PLUS (K160281), OSSIX® VOLUMAX (K153549)

IV. Device Description

OSSIX™ BONE is a biodegradable, osteoconductive, and biocompatible bone grafting material intended for guided tissue and bone regeneration. The OSSIX™ BONE matrix is composed of 80% synthetic crystalline non-sintered hydroxylapatite and 20% collagen, which is derived from veterinary certified pigs and is purified and cross-linked. OSSIX™ BONE is designed as a 3-D highly porous scaffold with physiological pH.

OSSIX™ BONE is packed in a double blister and an outer cardboard box and is sterilized by ethylene oxide; the shelf life of the device is 36 months.

Due to its porous and fibered microstructure, the matrix readily absorbs fluids, adheres to the surrounding tissues, and provides a scaffold that guides bone growth and regeneration. After implantation, OSSIX™ BONE undergoes gradual resorption in the body. Preclinical studies demonstrated that 50% or greater implant material remains at the 6-month time point.

OSSIX™ BONE is available in the following sizes: 0.125 CC (5x5x5 mm), 0.25 CC (5x5x10 mm) and 0.5 CC (5x10x10 mm).

OSSIX™ BONE is for prescription use only; it is intended to be implanted by trained dentists or oral surgeons in clinics during routine dental surgical procedures on adults with periodontal and bony defects of the maxillo-facial complex.

V. Indications for Use

OSSIX™ BONE is intended for the following uses:

- Augmentation or reconstructive treatment of the 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 the 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).

VI. Comparison of Technological Characteristics with the Predicate Device

OSSIX™ BONE has the same intended use and indications for use and similar technological characteristics as the predicate device, Geistlich Bio-Oss Collagen® (K122894). Both products are similar in their chemical composition (porcine type I collagen and crystalline hydroxylapatite), their structure (porous spongoius matrix made of hydroxylapatite particles embedded in a lattice network of collagen fibers), and mode of action (osteoconductive bone grafting material that acts as a scaffold for new bone growth and is slowly resorbed and replaced by new bone). Both products are designed as sterile, biodegradable, biocompatible, hydrophilic, moldable, trimmable, highly porous spongious matrices.

As outlined in more detail in the table below, the subject device differs slightly from the predicate device by the HA:collagen ratio, HA source (synthetic versus bovine), particle size, the sterilization method, and product size. The technological differences between the two products in composition, material characteristics and sterilization methodology do not affect the product performance as was demonstrated by the biocompatibility, bench, and animal studies.

Thus, the subject device is substantially equivalent to the predicate device.

Feature	OSSIX™ BONE	Geistlich Bio-Oss Collagen®
Intended use/ Indications for use	• Augmentation or reconstructive treatment of the 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 the 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).	• 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 the 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).
Mode of action	Conductive bone grafting material	Conductive bone grafting material
Design	Sterile, biodegradable, biocompatible, hydrophilic, moldable, trimmble, highly porous spongious matrix	Sterile, biodegradable, biocompatible, hydrophilic, moldable, trimmble, highly porous spongious matrix
Composition and source of materials	Crystalline synthetic hydroxyapatite (80%) combined with porcine type I collagen (20%)	Crystalline bovine derived hydroxyapatite (90%) combined with porcine type I collagen (10%)
Porosity	High porosity	High porosity
Density	2-3 g/cm^3	2-3 g/cm^3
Particle size	1 - 10 µm	250 - 1000 µ
Form	Block	Block
Max load	About 40 N	About 40 N
Sterility	ETO	ɤ-irradiation
Resorption profile	Slow resorption	Slow resorption
Prescription designation	Rx	Rx
Reusability	Single use only	Single use only
Product Size	0.125 cc 0.25 cc 0.5 cc	100 mg block 250 mg block 500 mg block
Unit package	Double blister	Double blister
Environment of use	OSSIX™ BONE should only be used by trained dentists or oral surgeons.	Geistlich Bio-Oss Collagen® should only be used by trained dentists or oral surgeons.
Intended patient population	Adults	Adults
Frequency and duration of use	Routine procedure	Routine procedure

Shelf life	The expiration date of the device is indicated on the outer box and the internal blister. The product has a 36-month shelf life.	The expiration date of the device is indicated on the outer box and the internal blister.

VII. Summary of Data to Support Substantial Equivalence

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing
The biocompatibility evaluation of OSSIX™ BONE was conducted in accordance with the FDA Guidance Use of International Standard ISO 10993-1, 2016, and International Standard ISO10993-1:2009 (Cor 1:2010) Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing. The final sterile device was tested for:

- cytotoxicity,
- pyrogenicity,
- sensitization,
- intracutaneous reactivity,
- genotoxicity,
- implantation,
- systemic toxicity (acute), subchronic toxicity,
- chronic toxicity.

OSSIX™ BONE is categorized as an implant device in contact with bone/tissue.

Sterility validation
The sterilization process is established and validated according to:

- ISO 11135:2014 Sterilization of health-care products -- Ethylene oxide -- Requirements for the development, validation and routine control of a sterilization process for medical devices.

The ability of the packaging to maintain the sterility of the product was demonstrated in packaging and shelf life studies.

Viral inactivation studies were conducted to demonstrate the ability of the manufacturing process to remove or inactivate viruses.

***In vitro* product characterization**
The *in vitro* product characterization testing was performed to demonstrate substantial equivalence of the subject device to its predicate device, as summarized in the table below.

Test	Method
Scanning Electron Microscope (SEM)	Microscopic appearance of OSSIX™ BONE and the predicate was performed using A Scanning Electron Microscope.
X-ray Diffraction (XRD)	The crystalline structure of the hydroxylapatite of OSSIX™ BONE and the predicate was measured using an XRD instrument.
Mechanical properties (compression)	The capability of OSSIX™ BONE and Geistlich Bio-Oss Collagen® to withstand pressure (compression resistance) was tested on using a tensile machine.
Chemical Analysis before and after manufacturing process	Elemental analysis of OSSIX™ BONE and Geistlich Bio-Oss Collagen® for calcium, oxygen and phosphorus was performed by means of energy-dispersive X-ray spectroscopy (EDS).
Infra-Red spectroscopy before and after manufacturing process	The FT-IR (Fourier Transform Infrared spectroscopy) analysis of OSSIX™ BONE and Geistlich Bio-Oss Collagen® was performed by using a Fourier transform infrared spectroscopy (FTIR) spectrophotometer.
Amino acid analysis	Amino acid analysis was performed using an amino acid analyzer.
Porosity, density	Mercury intrusion porosity meter.

The HA component conforms to the following standards:

- ISO 13779-3:2008, Implants for surgery – Hydroxyapatite – Part 3: Chemical analysis and characterization of crystallinity and phase purity;
- ASTM F1185-3:2014, Standard specification for composition of Hydroxylapatite for surgical implants.

Animal study

An *in vivo* animal study was conducted in an L-shape buccal mandibular defect model system in Beagle dogs to evaluate the *in vivo* performance and degradation of the device to support substantial equivalence. The study was conducted on 19 animals followed up for 1, 3 and 6 months. The performance of the subject OSSIX™ BONE in this study was compared to the predicate device, Geistlich Bio-Oss Collagen®, using a cleared OSSIX™ PLUS membrane in both treatments. The subject and predicate devices performed similarly in an L-shape buccal mandibular defect model system in Beagle dogs.

VIII. Conclusion

The subject and predicate devices have the same intended use/indications for use and substantially similar technological characteristics and principles of operation. In addition, minor technological differences between the two products do not affect the product performance, as supported by the results of the non-clinical data provided within the 510(k) submission, as summarized above. Therefore, the subject OSSIX™ BONE is substantially equivalent to the predicate device.