PURGO BIOLOGICS INC.
Hana Jung
RA Manager
E-607, 700, Pangyo-ro, Bundang-gu
Seongnam-si, Gyeonggi-do, Korea

July 20, 2018

Re: K173188
Trade/Device Name: The Graft Bone Substitute
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: Class II
Product Code: NPM
Dated: June 14, 2018
Received: June 21, 2018

Dear Hana Jung:

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.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mary S. Runner -S

FDA

For Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173188

Device Name
THE Graft Bone Substitute

Indications for Use *(Describe)*
THE Graft Bone Substitute is intended for use as a bone grafting material in dental surgery such as:
- Filling of extraction sockets to enhance preservation of the alveolar ridge
- Elevation of maxillary sinus floor

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary
K173188

I. SUBMITTER

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Date Revised: 7-20-2018

II. DEVICE

Name of Device: THE Graft Bone Substitute
Common or Usual Name: Bone Grafting Material
Classification Name: Bone Grafting Material, Animal Source (21 CFR 872.3930)
Regulatory Class: Class II (special controls)
Product Code: NPM

III. PREDICATE DEVICE

Collagen Matrix Inc. Porcine Anorganic Bone Mineral, K140714

Reference device: Bio-Oss® , K952617 (Geistlich-Pharma)

IV. SPECIAL CONTROLS

FDA Guidance “Class II Special Controls Guidance Document: Dental Bone Grafting Material Devices; Guidance for Industry and FDA Staff” was followed during the preparation of this submission.

V. DEVICE DESCRIPTION

THE Graft Bone Substitute is a resorbable bone graft material made of porcine cancellous bone consisting of Hydroxyapatite(HA).
THE Graft Bone Substitute is a natural and porous bone mineral matrix available in cancellous granules packaged in a vial or syringe. It is manufactured by removal of most organic components from porcine bone. The composition of THE Graft Bone Substitute meets the requirements of ASTM F1581 Standard Specification for Composition of Anorganic Bone for Surgical Implants. Due to its natural structure of macro and microscopic structures, the anorganic bone mineral of THE Graft Bone Substitute is physically and chemically comparable to the mineralized matrix of human bone. When packed into a bony site, THE Graft Bone Substitute is gradually resorbed and replaced with new bone during the healing process. The formation and ingrowth of new bone at the implantation site of THE Graft Bone Substitute is due to its trabecular architecture, interconnecting macro and micro pores and its natural consistency.
THE Graft Bone Substitute is supplied sterile, non-pyrogenic, and for single use only.

VI. INDICATIONS FOR USE

THE Graft Bone Substitute is intended for use as a bone grafting material in dental surgery such as:
- Filling of extraction sockets to enhance preservation of the alveolar ridge
- Grafting of maxillary sinus floor

VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

THE Graft Bone Substitute is substantially equivalent to the predicate device; Porcine Anorganic Bone Mineral K140714, in which the basic features, raw materials, material composition, intended uses, technological characteristics and performance characteristics are similar.
THE Graft Bone Substitute and the predicate device have similar Indications for Use. Both devices are intended for the same population and sterilized by gamma irradiation. The devices are made of biocompatible calcium phosphate bone mineral derived from porcine cancellous tissue adequate for bone formation. The devices feature trabecular-like characteristics, including interconnected macro and micro pores.

Device and Predicate Comparison Table			
Item	**THE Graft**	**ZCORE; K140714**	**Bio-Oss; K952617**
Indications for Use	THE Graft Bone Substitute is intended for use as a bone grafting material in dental surgery such as: - Filling of extraction sockets to enhance preservation of the alveolar ridge - Grafting of maxillary sinus floor	Porcine Anorganic Bone Mineral is intended for use in dental surgery. The products may be used in surgical procedures such as: - Augmentation or reconstructive treatment of 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	Geistlich Bio-Oss® is intended for the following uses: - 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); and - Filling of peri-implant defects in conjunction with products intended for Guided Bone Regeneration (GER).
Material Source	Porcine	Porcine	Bovine
Materials Composition	Calcium phosphate	Calcium phosphate	Calcium phosphate
Mineral Structure	Hydroxyapatite containing Carbonate	Carbonate apatite	Hydroxyapatite
Form	Granules	Granules	Granules
Color	White	White	White
Physical Appearance	Porous, irregular-shaped particles	Porous, irregular-shaped particles	Porous, irregular-shaped particles
Particle Size Range	0.2 – 0.355 mm, 0.25mm – 1.0mm or 1.00mm – 2.0mm	0.25mm – 1.0mm or 1.00mm – 2.0mm	0.25mm – 1.0mm or 1.00mm – 2.0mm
Resorption Profile	Gradual resorption	Gradual resorption	Gradual resorption
Package	Glass Vial or Glass Syringe in a single Tyvek Pouch	Plastic Jar in a single Blister Tray with Tyvek Lid	Glass Vial in a single Blister Tray with Tyvek Lid
Sterility	Sterile, SAL 10^{-6} Gamma irradiation (ISO 11137)	Sterile, SAL 10^{-6} Gamma irradiation (ISO 11137)	Sterile, SAL 10^{-6} Gamma irradiation (ISO 11137)
Pyrogenicity	Non-pyrogenic	Non-pyrogenic	Non-pyrogenic
Single Use/Reuse	Single use only	Single use only	Single use only

VIII. PERFORMANCE DATA

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

Mechanical and Physical testing

Non-clinical laboratory performance testing was conducted to confirm that the composition of THE Graft Bone Substitute meets the requirements of ASTM F1581 Standard Specification for Composition of Anorganic Bone for Surgical Implants. This testing was performed in accordance with FDA's Class II Special Controls Guidance Document: Dental Bone Grafting Material Devices, issued on April 28th of 2005.

Biocompatibility testing

The biocompatibility evaluation for THE Graft Bone Substitute was conducted in accordance with the International Standard ISO 10993-1:2009 "Biological Evaluation of Medical Devices Part-1: Evaluation and Testing Within a Risk Management Process" as recognized by FDA to further ensure substantial equivalence with the predicate device.
Assessment of the candidate device included the following tests:

- Cytotoxicity (ISO 10993-5)
- Sensitization Test (ISO 10993-10)
- Intracutaneous Reactivity (ISO 10993-10)
- Acute Systemic Toxicity (ISO 10993-11)
- Subchronic Toxicity Test (ISO 10993-11)
- Genotoxicity (ISO 10993-3)
- Implantation Test (ISO 10993-6)
- Pyrogen Testing
- Shelf-Life

Sterilization

In accordance with ISO 11137-1, THE Graft Bone Substitute is sterilized with gamma radiation with the use of minimum dose 25 kGy for sterility assurance level of 10^{-6}.

- Sterilization Validation (ISO 11137-2)
- Endotoxin Test
- Packaging Validation

Viral Inactivation

Viral safety validation was performed and the result showed complete inactivation of viruses.

Non-clinical and Clinical Evaluation

In-vivo dog model was performed as well as Clinical data was provided to assess THE Graft and the predicate device as implantable materials.

All of the acceptance criteria were met.

IX. CONCLUSIONS

Based on the information provided within this 510(k) submission, Purgo Biologics Inc. concludes that THE Graft is substantially equivalent to the legally marketed predicate device listed according to the requirements of the Federal Food, Drug, and Cosmetic Act.