February 14, 2020

Purgo Biologics Inc.
Eun Kim
R&D Staff
E-607, 700, Pangyo-ro
Bundang-gu
Seongnam-si, 13516 Kr

Re: K191737
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: July 1, 2020
Received: August 1, 2020

Dear Eun Kim:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Srinivas Nandkumar, Ph.D.
Director
DHT1B: Division of Dental Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(K) Number (if known): K191737

Device Name: The Graft Bone Substitute

Indication 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
- Elevation of maxillary sinus floor

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)
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K191737
510(k) Summary

Submitter

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Device Information

- Trade Name: The Graft Bone Substitute
- Common Name: Bone Grafting Material
- Classification Name: Bone Grafting Material, Animal Source
- Product Code: NPM
- Panel: Dental
- Regulation Number: 21 CFR 872.3930
- Device Class: Class II
- Date Prepared: 02/13/2020

Predicate Devices:

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

- K173188, The Graft Bone Substitute by Purgo Biologics Inc.
- K162158, Porcine Anorganic Bone Mineral in Delivery Applicator by Collagen Matrix Inc.

Indication 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
- Elevation of maxillary sinus floor

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 vial or syringe. It is produced by removal of all 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 favored 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.

THE Graft Bone Substitute is not intended to be marketed or sold with multiple components and/or accessories.

List of product models seeking clearance in this submission:

Type	Model No.	Particle Size (mm)	Capacity	Packaging
Cancellous Granules	TG-AS25	0.25 ~ 1.00 mm	0.25 cc	Syringe + Tyvek Pouch
	TG-AS05		0.50 cc	
	TG-AS10		1.00 cc	
	TG-BS25	1.00 ~ 2.00 mm	0.25 cc	Syringe + Tyvek Pouch
	TG-BS05		0.50 cc	
	TG-BS10		1.00 cc	

Previous submission information:

Previous submission: THE Graft Bone Substitute(K173188)

This submission is to change syringe package material from the predicate.
The glass vial models of THE Graft Bone Substitute remains unchanged from the previous submission K173188.
There is no significant difference between the predicate device and subject device. It is substantially equivalent with the subject device in design, function, material, operational principle.

Summary of Technological Characteristics:

THE Graft Bone Substitute is substantially equivalent to the predicate device; Porcine Anorganic Bone Mineral, in which the basic features, raw materials and intended uses are the same. Any differences between THE Graft Bone Substitute and the predicate device are considered minor or insignificant. Therefore, it does not raise any questions concerning safety and effectiveness when comparing the subject device to its predicate device.

The table in the following pages summarizes the comparison of technical characteristics.

	Device and Predicate Comparison Table		
Descriptive Information	**THE Graft Bone Substitute (This submission)**	**THE Graft Bone Substitute (K173188)**	**Porcine Anorganic Bone Mineral in Delivery Applicator (K162158)**
Intended Use	**THE Graft Bone Substitute is intended for use as a bone grafting material in dental surgery such as:** - **Filling of infrabony periodontal defects** - **Elevation of maxillary sinus floor**	**THE Graft Bone Substitute is intended for use as a bone grafting material in dental surgery such as:** - **Filling of infrabony periodontal defects** - **Elevation 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**
Material Source	Porcine Bone	Porcine Bone	Porcine Bone
Materials Composition	Hydroxyapatite	Hydroxyapatite	Calcium phosphate
Mineral Structure	Hydroxyapatite	Hydroxyapatite	Carbonate apatite

Form	Granules	Granules	Granules
Color	White	White	White
Physical Appearance	Porous, irregular-shaped particles	Porous, irregular-shaped particles	Porous, irregular-shaped particles
Product Sizes	0.25cc, 0.5cc, 1.0cc,	0.15g, 0.25g, 0.50g, 1.00g, 2.00g, 5.00g, 0.18cc, 0.25cc, 0.5cc, 1.0cc, 2.0cc, and 5.0cc	0.25cc and 0.5cc
Particle Size Range	0.25 – 1 mm and 1 - 2 mm	0.2 – 0.355 mm, 0.25 – 1 mm and 1 - 2 mm	0.25 – 1 mm and 1 - 2 mm
pH	7.0	7.0	7.3 ± 0.1
Resorption Profile	Gradual resorption	Gradual resorption	Gradual resorption
Package	Polypropylene syringe in a single Tyvek Pouch	Glass Vial or glass syringe in a single Tyvek Pouch	Pre-loaded into plastic delivery applicator
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

Non-clinical testing 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: "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.

The device used for testing is as follows:
THE Graft Bone Substitute, Syringe Model
Model Number: TG-AS10
Particle size: 0.25 ~ 1.00 mm
Volume: 1.00 cc
Primary packaging: Polypropylene Syringe
Secondary packaging: Tyvek pouch
Tertiary packaging: Product carton box

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)
- Pyrogen Testing (ISO 10993-11 / USP <151>, <85>)
- Shelf-Life

All of the acceptance criteria were met.

Conclusion:
Based on the information provided within this Traditional 510(k) submission, Purgo Biologics Inc. concludes that polypropylene syringe models of THE Graft Bone Substitute is substantially equivalent in safety and performance to the legally marketed predicate device listed according to the requirements of the Federal Food, Drug, and Cosmetic Act.