Purgo Biologics Inc.
Byungsun Kim
RA Team Manager
#812, 27 Dunchon-daero 457beon-gil, Jungwon-gu
Seongnam-si, Gyeonggi-do 13219
KOREA, SOUTH

July 24, 2024

Re: K230305
Trade/Device Name: THE Graft Collagen
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: Class II
Product Code: NPM
Dated: June 21, 2024
Received: June 24, 2024

Dear Byungsun 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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Sherrill Lathrop Blitzer

for Andrew Steen
Assistant Director
DHT1B: Division of Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230305

Device Name
THE Graft Collagen

Indications for Use *(Describe)*

THE Graft Collagen is recommended for:
- Filling of extraction sockets to enhance preservation of the alveolar ridge.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

07/24/2024

1. Company

	Submitter
Name	Purgo Biologics Inc.
Address	#812, 27 Dunchon-daero 457beon-gil, Jungwon-gu, Seongnam-si, Gyeonggi-do, Korea 13219
Phone/Fax	Tel. +82-70-4827-0451, Fax. +82-70-8673-0660
Contact person	Byungsun Kim / RA kimbs@purgobio.com
Summary Date	07/24/2024

2. Device Name

Trade name	:	THE Graft Collagen
Regulation number	:	21 CFR 872.3930
Regulation Description	:	Bone Grafting Material
Product code	:	NPM
Classification name	:	Bone Grafting Material, Animal Source
Device class	:	Class II
Classification Panel	:	Dental

3. Predicate Device

Primary predicate device

K122894 Bio-Oss® Collagen

Reference predicate device

K173188 The Graft Bone Substitute

4. Description

THE Graft Collagen, composed of porcine derived bone mineral matrix from cancellous bone and Type I Collagen from porcine tendon. The bone mineral matrix is similar to physical and chemical aspects of the mineralized matrix of human bone. Hydrated collagen components have viscosity that facilitates for blending of the bone mineral matrix. With this characterization, it can be trimmed and/or molded to the various shapes of defects. THE Graft Collagen is sterilized using gamma irradiation and recommended for the patient who needs filling of bone defects and bone augmentation.

THE Graft Collagen is available in various sizes.

Type	Sizes
Block	(Height x Length x Width) 3 x 5 x 7 mm, 5 x 5 x 5 mm, 5 x 5x 10 mm, 7 x 7x 7 mm

THE Graft Collagen contains 85% The Graft Bone Substitute (K173188) granules and 15% porcine collagen in a block form. The Graft Bone Substitute (K173188) is a porous bone mineral matrix available in cancellous granules made of porcine bone. Granules serve as a scaffold for new bone, and collagen holds the granules not to break away from the implanted site and facilitates handling.

5. Indication for use

THE Graft Collagen is recommended for:

- Filling of extraction sockets to enhance preservation of the alveolar ridge.

6. Summary of Data to Support Substantial Equivalence

Non-clinical performance testing of the subject device was conducted to demonstrate substantial equivalence to the predicate devices. The following performance date are provided in support of the substantial equivalence determination.

• Bench testing was performed to evaluated the physicochemical properties of the device as followings:

- Ca/P ratio

- Residue on ignition
- Heavy metal
- pH
- Compressive strength

• Biocompatibility was evaluated in accordance with ISO 10993-1 as followings:
- Cytotoxicity per ISO 10993-5
- Irritation per ISO 10093-10
- Sensitization per ISO 10993-10
- Genotoxicity per ISO 10993-3
- Acute toxicity per ISO 10993-11
- Subchronic toxicity per ISO 10993-11
- Implantation per ISO 10993-6
- Pyrogenicity per ISO 10993-11

• Material-mediated pyrogenicity testing per ISO 10993-11 and endotoxin testing (LAL, Limulus Amebocyte Lysate) per USP <85> were performed demonstrating non-pyrogenicity.

• Sterilization process validation was performed accordance with ISO 11137 demonstrating a sterility assurance level (SAL) of 10^{-6}.

• Real time aging shelf-life study was performed accordance with ISO 11607 demonstrating product stability and packaging integrity.

• The control of animal origin materials was performed as followings:
- Controls on sourcing, collection, and handling per ISO 22442-2
- Viral Inactivation per ISO 22442-3

The in-vivo performance of the subject device in a beagle mandibular intraoral model was compared to that of the primary predicate device, Bio-Oss Collagen. Histology, histomorphometry and Micro-CT analyses were conducted for the subject device, primary predicate device and negative control at 4, 8, 12, 16 and 24 weeks. The results demonstrated that the performance of the subject and primary predicate devices was substantially equivalent.

No clinical data from clinical trial were included in this submission.

7. Technological Characteristics and Substantial Equivalence

The following comparison table of the technological characteristics of the subject device and the predicate device outlines and provides the substantial equivalency of the subject device and the predicate.

Comparison of Characteristics

	Subject device	**Primary predicate device**	**Reference predicate device**	**Discussion**
Device name	THE Graft Collagen	Bio-Oss® Collagen	The Graft Bone Substitute	-
Manufacturer	Purgo Biologics Inc.	Geistlich Pharma Ag	Purgo Biologics Inc.	-
510(k) Number	K230305	K122894	K173188	-
Product Code	NPM	NPM	NPM	Same
Indication for Use	1) Filling of extraction sockets to enhance preservation of the alveolar ridge.	1) Augmentation or reconstructive treatment of the alveolar ridge. 2) Filling of periodontal defects. 3) Filling of defects after root resection, apicoectomy, and cystectomy. 4) Filling of extraction sockets to enhance preservation of the alveolar ridge. 5) Elevation of the maxillary sinus floor. 6) Filling of periodontal defects in conjunction with products intended for	1) Filling of extraction sockets to enhance preservation of the alveolar ridge. 2) Grafting of maxillary sinus floor	Equivalent The indication for Use of the subject device is a subset of that of the primary predicate device.

		Guided Tissue Regeneration (GTR) and Guided Bone Regeneration (GBR). 7) Filling of peri-implant defects in conjunction with products intended for Guided Bone Regeneration (GBR).		
Function	The Graft Collagen contains 85% The Graft Bone Substitute granules and 15% porcine collagen. Granules serve as a scaffold for new bone. Collagen holds the granules and facilitates handling.	Bio-Oss® Collagen contains 90% Bio-Oss® granules and 10% porcine collagen. Granules serve as a scaffold for new bone. Collagen holds the granules and facilitates handling.	The Graft Bone Substitute granules serve as a scaffold for new bone.	Equivalent
Material Composition	• Porcine-derived hydroxyapatite bone mineral • Porcine-derived type I collagen	• Bovine-derived hydroxyapatite bone mineral • Porcine-derived type I collagen	• Porcine-derived hydroxyapatite bone mineral	Equivalent
Form	Block	Block	Granules	Equivalent
Color	White to off-white	White to off-white	White to off-white	Same
Size	3 x 5 x 7 mm, 5 x 5 x 5 mm, 5 x 5x 10 mm, 7 x 7x 7 mm,	2.5 x 5 x 7.5 mm (50mg) 5 x 5 x 7 mm (100mg) 7 x 7 x 7 mm (250mg) 10 x 10 x 7 mm (500mg)	0.15g, 0.25g, 0.5g, 1.0g, 2.0g, 5.0g	Equivalent
Biocompatibility	Biocompatible	Biocompatible	Biocompatible	Same
Sterilization	Gamma Irradiation	Gamma Irradiation	Gamma Irradiation	Same
Sterility	Sterile, SAL 10^{-6}	Sterile, SAL 10^{-6}	Sterile, SAL 10^{-6}	Same

Pyrogenicity	Non-pyrogenic	Non-pyrogenic	Non-pyrogenic	Same
Use	Prescription	Prescription	Prescription	Same
Single Use Only	Yes	Yes	Yes	Same

The subject device is substantially equivalent to the primary predicate device K122894 in indication for use, function, material, design, biocompatibility and sterilization. Differences include the size range, composition of bone mineral and collagen, and animal origin of bone mineral.

Discussion on the differences

• Size range

- The subject and primary predicate devices can be trimmed to fit the defect shapes, so the sizes do not affect usage.

• Composition of bone mineral and collagen

- The subject device contains 85% The Graft Bone Substitute (K173188) granules and 15% porcine collagen. The primary predicate device contains 90% Bio-Oss® granules and 10% porcine collagen. In both devices, granules serve as a scaffold for new bone and collagen is used to hold the granules. So, composition of collagen does not affect to the intended use.

• Animal origin of bone mineral

- Bone mineral of the subject device is derived from porcine and that of the predicate device is derived from bovine. The animal origin is different, but the safety of material was verified through biocompatibility tests and virus inactivation validation.

8. Conclusion

Based on the information provided, the subject device is substantially equivalent to the primary predicate device.