October 6, 2023

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

Re: K230091
Trade/Device Name: THE Cover
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: Class II
Product Code: NPL
Dated: September 6, 2023
Received: September 7, 2023

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)*
K230091

Device Name
THE Cover

Indications for Use *(Describe)*

THE Cover is recommended for:
- Covering of immediate or delayed extraction socket 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

10/05/2023

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	10/05/2023

2. Device Name

Trade name	:	THE Cover
Regulation number	:	21 CFR 872.3930
Regulation Description	:	Bone Grafting Material
Product code	:	NPL
Classification name	:	Barrier, Animal Source, Intraoral
Device class	:	Class II
Classification Panel	:	Dental

3. Predicate Device

Primary predicate device

K192042 Bio-Gide®

4. Description

THE Cover Resorbable Collagen Membrane is a white, pliable membrane consisting of fibrous collagen matrix purified from porcine tendon. THE Cover act as a barrier between the gingival and the new bone that can facilitate proper bone regeneration. As soft tissues tend to grow faster than the bone can regenerate, the membrane can help protect the bone graft particles from this faster growing connective tissue. As collagen membrane will be dissolved, no additional operation is necessary. THE Cover does not have a distinction between face and back.
THE Cover is available in various sizes.

Size	Thickness
15 x 20 mm	0.3 mm, 0.5 mm
15 x 30 mm	
25 x 30 mm	
30 x 40 mm	

5. Indication for use

THE Cover is recommended for:

- Covering of immediate or delayed extraction socket to enhance preservation of the alveolar ridge.

6. Summary of Data to Support Substantial Equivalence

The determination of substantial equivalence was based on an assessment of non-clinical performance data obtained from in vitro characterization studies, an in vivo animal study, and biocompatibility testing of the subject device.

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

- Appearance and dimension (Size, Thickness)
- Composition and purity (Amino acid analysis, Heavy metal, Fat content, Loss on drying, Collagen content)
- Enzymatic (Collagenase degradation, Trypsin resistance)
- Structural (Denaturing temperature)

- Mechanical properties (Tensile strength, Tear 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
  - Material mediated pyrogenicity per ISO 10993-11

- Sterilization process validation was performed in accordance with ISO 11137-1 and ISO 11137-2 demonstrating a sterility assurance level (SAL) of 10^{-6}.

- Real time aging shelf-life study was performed in accordance with ISO 11607-1 and ISO 11607-2 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

An in vivo animal study conducted in a beagle mandibular intraoral model comparing THE Cover and the predicate device at 4, 8, 12, 16 and 24 weeks demonstrated that both devices were fully resorbable and acted as a barrier preventing ingrowth of soft tissue into the bone defect.
Membrane degradation rate and performance of THE Cover were no different to the predicate when evaluated by histological and histomorphometric analysis, providing in vivo evidence for substantial equivalence of the two devices.

No clinical data 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**	**Discussion**
Device name	THE Cover	Bio-Gide®	-
Manufacturer	Purgo Biologics Inc.	Geistlich Pharma Ag	-
510(k) Number	K230091	K192042	-
Product Code	NPL	NPL	Same
Indication for use	THE Cover is recommended for: - Covering of immediate or delayed extraction socket to enhance preservation of the alveolar ridge.	Bio-Gide® is recommended for: 1) Augmentation around implants placed in immediate extraction sockets 2) Augmentation around implants placed in delayed extraction sockets 3) Localized ridge augmentation for later Implantation 4) Alveolar ridge reconstruction for prosthetic treatment 5) Filling of bone defects after root resection, cystectomy, removal of retained teeth 6) Guided bone regeneration in dehiscence Defects 7) Guided tissue regeneration procedures in Periodontal defects	Equivalent The indication for the subject device is a subset of that for the predicate device.
Function	Functions as a barrier when applied between Alveolar bone and soft tissue. The membrane serves as a bioresorbable scaffold.	Functions as a barrier when applied between Alveolar bone and soft tissue. The membrane serves as a bioresorbable scaffold.	Same

Operating Principles	• Cell-occlusive • Implantable • Resorbable • Biocompatible	• Cell-occlusive • Implantable • Resorbable • Biocompatible	Same
Resorption time	Substantially resorbed by 24 weeks	Substantially resorbed by 24 weeks	Equivalent
Material	Porcine Derived Collagen	Porcine Derived Collagen	Same
Collagen source	Porcine tendon	Porcine	Equivalent Using the collagen derived from porcine is the same, but the parts of tissue used are different.
Form	Membrane	Membrane	Same
Color	White to off-white	White to off-white	Same
Crosslink	Non-crosslinked	Non-crosslinked	Same
Size	15 x 20, 15 x 30, 20 x 30, 30 x 40	13 x 25, 25 x 25, 30 x 40, 40 x 50	Equivalent Both devices are provided in various sizes for intra-oral surgical procedures
Sterilization	Gamma Irradiation	Gamma Irradiation	Same
Sterility	Sterile, SAL 10^{-6}	Sterile, SAL 10^{-6}	Same
Shelf-life	3 years	3 years	Same
Use	Prescription	Prescription	Same
Single Use Only	Yes	Yes	Same

The subject device is substantially equivalent to the primary predicate device K192042 in indication for use, function, material, design and sterilization. The collagen composed both devices are derived from porcine, but the parts of animal tissue used are different. The safety of material and device were 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.