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

5/11/23

Re: K222549
Trade/Device Name: OpenTex
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: Class II
Product Code: NPK
Dated: April 10, 2023
Received: April 11, 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 (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,

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

Indication for use

510(k) Number: K222549

Device Name: OpenTex

Indication for use:

OpenTex is a temporarily implantable material (non-resorbable) for as a space-making barrier in the treatment of periodontal defects.

Prescription Use ___√___ **AND/OR** **Over-The-Counter Use** _____

(Part 21 CFR 801 Subpart D) **(21 CFR 801 Subpart C)**

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Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

05/10/2023

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	05/10/2023

2. Device Name

Proprietary name	:	OpenTex
Regulation number	:	21 CFR 872.3930
Regulation Description	:	Bone Grafting Material
Product code	:	NPK
Classification name	:	Barrier, Synthetic, Intraoral
Device class	:	Class II
Classification Panel	:	Dental

3. Predicate Device

Primary predicate device

K160493 Salvin CytoSurg™ Non-Resorbable PTFE Membrane

Reference device

K964342 Cytoplast GBR

4. Indication for use

OpenTex is a temporarily implantable material (non-resorbable) for as a space-making barrier in the treatment of periodontal defects.

5. Description

OpenTex is a non-resorbable PTFE membrane composed of proprietary 100% polytetrafluoroethylene (PTFE) sheet with inert biological features and predictable barrier effect.
OpenTex is designed to function as a physical barrier to avoid gingival cell invasion, thus providing a favorable environment for neovascularization and bone derived cells to repopulate and repair the defect. Since space-making is critical to this procedure, the membrane is sufficiently stiff to prevent spontaneous collapse but supple enough to conform easily to tissue contours.
OpenTex is supplied sterile and intended for single use only. It is available in various sizes as shown below.

Size	Thickness	Packaging
12 x 20 mm	0.16 mm	1ea / box 5ea / box 10ea / box
14 x 24 mm		
17 x 25 mm		
20 x 25 mm		
24 x 30 mm		
30 x 40 mm		

6. Performance Data

Non-clinical testing was performed in accordance with FDA recognized consensus standards and FDA guidance as applicable.

• Performance testing was performed to demonstrate substantial equivalence of the subject device to its primary predicate device as table below. The test results of the subject device met the criteria and was equal or higher than that of the predicate device.

Test item	Test method	Criteria	Results
pH	pH measurement test	Difference between the blank and the extracts < 1.5 (Internal) * pH measured - Blank: 6.23 - Subject device: 6.23 - Predicate device: 6.21	The results of both devices met the criteria.
Dissolution / Solubility	Evaporation residue test	Evaporation residue of the extraction liquid ≤ 1.0mg	The results of both devices met the criteria.
Tensile strength	ASTM D882	≥ 34 MPa (Internal)	The result of the subject device met the criteria and was higher than that of predicate device.
Tear resistance	ISO 6383-1	≥ 1.5 kgf/mm (Internal)	The result of the subject device met the criteria and was higher than that of predicate device.
Suture retention strength	ANSI/AAMI/ISO 7198	Criteria for the subject device was established as equivalent to result of predicate device.	The result of the subject device was higher than that of predicate device.

- Biocompatibility was evaluated in accordance with ISO 10993 series as followings.
  - Biocompatibility risk assessment per ISO 10993-1
  - 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
  - Subacute toxicity per ISO 10993-11
  - Implantation per ISO 10993-6
  - Material mediated pyrogenicity per ISO 10993-11

• EO(Ethylene Oxide) gas sterilization process validation was performed accordance with ISO 11135 demonstrating a sterility assurance level (SAL) of 10^{-6}.

No clinical data were included in this submission.

7. Technological Characteristics

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	**Predicate device**		**Discussion**
		Primary predicate device	**Reference device**	
Device name	OpenTex	Salvin CytoSurg™ Non-Resorbable PTFE Membrane	Cytoplast GBR	-
Manufacturer	Purgo Biologics Inc.	Salvin Dental Specialties	Osteogenics Biomedical, Inc.	-
510(k) Number	New Device	K160493	K964342	-
Indication for use	OpenTex is a temporarily implantable material (non-resorbable) for as a space-making barrier in the treatment of periodontal defects.	The Salvin CytoSurg™ Non-Resorbable PTFE Membrane is temporarily implantable material (non-resorbable) for as a space-making barrier in the treatment of periodontal defects.	A temporarily implantable material (non-resorbable) for use as a space-making barrier in the treatment of periodontal defects.	Substantially equivalent
Materials	PTFE	PTFE	PTFE	Equivalent The subject and predicate devices are composed of PTFE.
Form	Membrane (Plain, Textured type)	Membrane (Textured type)	Membrane (Textured type)	Equivalent The subject device is provided in plain and textured type while the predicate devices are provided in textured type. Textured type is manufactured by giving

				PTFE sheet a textured surface through the 'patten input' process. Because this process does not affect the properties of PTFE sheet, the property of plain and textured type is same. The equivalence of performance to the predicate device was verified trough the bench testing.
Size	12 x 20 mm, 14 x 24 mm 17 x 25 mm, 20 x 25 mm 24 x 30 mm, 30 x 40 mm	12 x 24 mm, 25 x 30 mm	12 x 24 mm, 25 x 30 mm	Equivalent The subject and predicate devices are provided in various sizes for intra-oral surgical procedures.
Thickness	0.16 mm	0.25 mm	0.25 mm	Equivalent The subject is thinner than the predicate, but the equivalence of performance was verified trough the bench testing.
Sterilization	Sterile (ETO, SAL 10^{-6})	Sterile (ETO, SAL 10^{-6})	Sterile (ETO, SAL 10^{-6})	Identical
Shelf-life	5 years	Unknown	5 years	Equivalent The shelf-life of the subject device is equivalent to the referemce device.
pH	6.23	6.21	Unknown	Equivalent The performance test results of the subject device met the criteria and was equal or higher than that of the predicate device.
Dissolution / Solubility	0 mg	0 mg	Unknown	
Tensile strength	72.1524 MPa	33.8444 MPa	Unknown	
Tear resistance	5.9254 kgf/mm	1.288 kgf/mm	Unknown	
Suture retention strength	1.083 MPa	0.842 MPa	Unknown	
Use	Prescription	Prescription	Prescription	Identical
Single Use Only	Yes	Yes	Yes	Identical
Duration of implantation	Less than 30 days	Less than 30 days	Less than 30 days	Equivalent The subject and predicate devices are temporarily implantable materials and intended to be removed within 30 days.

The subject device is substantially equivalent to the primary predicate device K160493 in indication for use, material, design(form), sterilization and duration of implantation. Both devices are provided

in various sizes for intra-oral surgical procedures. The subject device is thinner than the predicate devices, but the equivalence of performance was verified through tensile strength and tear resistance tests.

8. Conclusion

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