Kerecis
Gudmundur Sigurjonsson
CEO
Eyrargata 2
Isafjordur, 400
Iceland

9/30/22

Re: K213904
Trade/Device Name: Kerecis® Oral
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: Class II
Product Code: NPL
Dated: September 6, 2022
Received: September 7, 2022

Dear Gudmundur Sigurjonsson:

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,

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)*
K213904

Device Name

Kerecis® Oral

Indications for Use *(Describe)*

- Localized gingival augmentation to increase keratinized tissue (KT) around teeth or implants;
- Covering of implants placed in immediate extraction sockets;
- Covering of implants placed in delayed extraction sockets;
- Covering of bone defects after root resection and removal of retained teeth; and
- Guided tissue regeneration procedures in periodontal and recession defects.

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

Traditional Premarket Notification Submission (510(k)) Summary)
Prepared in accordance with 21 CFR § 807.92

1. Submitter Information

Sponsor Name:	Kerecis Limited
Sponsor Address:	Eyrargata 2 – PO Box 151, 400 Isafjordur, Iceland
Sponsor Telephone:	+011 354-419-8000
Establishment Registration:	301060025
Primary Contact Person:	Gudmundur Fertram Sigurjonsson
Contact Title:	Founder, Chairman, President & CEO
Email Direct:	gfs@kerecis.com
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Additional Contact Person:	Jennifer Michelle Chambers, MPA, PMP, RAC
Contact Title:	Senior Regulatory Specialist
Email Direct:	jchambers@kerecis.com

Date Summary Prepared:	September 30, 2022

2. Device Information

Trade Name (Proprietary):	Kerecis® Oral
Common (Usual):	Intraoral Surgical Graft
Classification Name:	Barrier, Animal Source, Intraoral
Device Classification:	Class II, 21 CFR § 872.3930
FDA Device Code:	NPL

3. Predicate Device and Reference Devices

Predicate Device

Company Name:	Ed. Geistlich Söhne Ag für Chemische Industrie
Device Name (proprietary):	MUCOGRAFT® Collagen Matrix
Device 510(k):	K073711

Reference Device

Company Name:	Kerecis
Device Name (proprietary):	Kerecis Gingiva Graft
Device 510(k):	K192612

4. Device Description

The subject device is an acellular resorbable fish dermal matrix, intended for use in periodontal surgical procedures to aid in soft tissue and bone regeneration. It is obtained from cod fish skin by a standardized controlled manufacturing process, and supplied in terminally sterile peel-pouch packaging in the following solid sizes:

- 15mm x 20mm
- 20mm x 30mm
- 30mm x 40mm

It is biocompatible, non-cross linked, and therefore resorbable, strong, flexible, and supports fixation by sutures and pins.

5. Intended Use

The subject device is indicated for:

- Localized gingival augmentation to increase keratinized tissue (KT) around teeth or implants;
- Covering of implants placed in immediate extraction sockets;
- Covering of implants placed in delayed extraction sockets;
- Covering of bone defects after root resection and removal of retained teeth; and
- Guided tissue regeneration procedures in periodontal and recession defects.

6. Technological Characteristics and Substantial Equivalence

Comparison with the predicate device (K073711), and the reference device (K192612), demonstrate that it is substantially equivalent with regards to: intended use, materials, design, and operational principle.

See Table 6.1. Kerecis Oral is comparison with predicate and reference devices.

Table 6.1. Kerecis Oral is comparison with predicate and reference devices.

	Subject Device	Predicate Device	Reference Device	Discussion
Device Name	**Kerecis Oral**	**Geistlich MUCOGRAFT Collagen Matrix**	**Kerecis Gingiva Graft**	N/A
510(k)	TBD	K073711	K192612	N/A
Regulation	21 CFR 872.3930	21 CFR 872.3930	21 CFR 872.3930	Same regulation
Device Class	II	II	II	Same device class
Product Code	NPL	NPL	NPL	Same product code
Device Classification	Barrier, Animal Source, Intraoral	Barrier, Animal Source, Intraoral	Barrier, Animal Source, Intraoral	Same device classification
Intended Use	indicated for: Localized gingival augmentation to increase keratinized tissue (KT) around teeth or implants; -Covering of implants placed in immediate extraction sockets; -Covering of implants placed in delayed extraction sockets;	indicated for: -Simultaneous use of GBR-membrane and implants -Covering of implants placed in immediate extraction sockets; -Covering of implants placed in delayed extraction sockets; -Localized ridge augmentation	indicated for: –Localized gingival augmentation to increase keratinized tissue (KT) around teeth or implants.	Intended use includes elements of the predicate and reference devices, supported by performance testing in canines, intended to demonstrate equivalence in the oral environment

	-Covering of bone defects after root resection and removal of retained teeth; -Guided tissue regeneration procedures in periodontal and recession defects.	for later implantation; -Alveolar ridge reconstruction for prosthetic treatment; -Covering of bone defects after root resection, cystectomy, removal of retained teeth; -Guided bone regeneration in dehiscence defects; and -Guided tissue regeneration procedures in periodontal and recession defects.		
Animal Origin Material	Fish: skin tissue, single layer sheet	Porcine: skin and connective tissue, double layer sheet	Fish: skin tissue, single layer sheet	Same animal species as reference
Biocompatibility	Yes	Yes	Yes	Biocompatibility testing performed per ISO 10993 series standards
NON-Pyrogenic	Yes	Yes	Yes	Materials-mediated pyrogenicity safe per ISO 10993 series standard
Tensile Strength	14.3 MPa	4.6 MPa	14.3 MPa	Meets tensile strength value of the predicate device per ASTM D638

Resorbable	Yes	Yes	Yes	All devices are resorbable per comparative performance data
Sizes	15x20 mm 20x30 mm 30x40 mm	15x20 mm 20x30 mm 30x40 mm	15x20 mm 20x30 mm 30x40 mm	Equivalent sizes by dimensional analysis
Sterilization	Ethylene Oxide	Gamma Irradiation	Ethylene Oxide	Traditional Sterilization Methods per ISO 11135 and ISO 11737-1. EO residual testing per ISO 10993-7
Sterility Assurance Level	10^{-6}	10^{-6}	10^{-6}	Equivalent SAL per ISO 11137 and ISO 11737
Shelf Life	3 years	3 years	3 years	Equivalent shelf life per ASTM F1980 and Q5C (R2)[ICH]
Mode of Action	Fixation	Fixation	Fixation	Equivalent mode of action per ANSI/AAMI/ISO 7198 and ASTM F-1839-08

7.

Performance Testing – BenchBench testing was performed following FDA guidance, "Preparation of a Premarket Notification Application for a Surgical Mesh" (1999). The following performance studies were conducted on representative product samples to verify that material properties remain unchanged and support substantial equivalence:

7.1 Morphology Observation

The subject device and the predicate device are based on the collagen rich animal tissue, piscine and porcine, respectively. Based on H&E staining, both materials are rich in collagen and porous, therefore favoring cellular infiltration. Scanning Electron Microscope (SEM) shows equivalent preserved collagen structure of the animal origin tissues used for both devices. Cross section of both devices showed that the porous surfaces in the skin derived collagen structure of both materials allows tissue adherence and promotes tissue regeneration by favoring cellular ingrowth when applied to soft tissue defect areas.

7.2. Cellular ingrowth comparison

Both materials were tested for cellular ingrowth capability by fibroblast seeding onto the materials in vitro cellular modes. Both materials showed favorable cellular infiltration of fibroblasts after 14 days

which is a key component for tissue augmentation and re-epithelization of defected keratinized tissue in the oral cavity.

7.3. Tensile Strength

The tensile strength of the subject device was determined to be comparable to the predicate device measured by ultimate tensile strength.

7.4. Heavy Metal Analysis

A heavy metal analysis was evaluated to show that the limits of cadmium (Cd), lead (Pb), arsenic (As) and mercury (Hg) contained within the subject device were acceptable under the ICH guidelines: Q3D Elemental Impurities-Guidance for Industry.

7.5. Dimensional Validation

Manufacturing dimensional validation was performed on three lots of the subject device where its dimension and thickness were tested. Kerecis has set the quality limits for a capability index to be > 1.33. All tested parameters met or exceeded the set goal.

7.6. Stability in a simulated physiological environment

A stability test was done in a simulated physiological oral environment (artificial saliva buffer) to investigate the dissolution of both material over time and to compare the effects that the products have on the pH levels and conductivity of the buffer over 24 hours. The subject device is structurally more stable than the predicate device since it dissolved slower than the predicate device at neutral pH 7.

7.7. Suture Pull-Out Strength

Consistent with recognized standard ANSI/AAMI/ISO 7198, The suture pull-out strength of the subject device meets or exceeds that of the predicate with a confidence of greater than 95%. The products are equivalent.

7.8. Pin Pull-Out Strength

Consistent with recognized standard ASTM F-1839-08, The pin pull-out strength of the subject device exceeds that of the predicate at a confidence level of greater than 95%. The products are equivalent.

7.9. Compression

In accordance with ASTM-F-1306, “Standard Test Method for Slow Rate Penetration Resistance of Flexible Barrier Films and Laminates”, the mechanical test for compressive strength was measured for the subject and predicate device. The compressive Peak-Load, Load-at-Break, Probe Penetration-at-Break, and Energy-to-Break of the subject device meet or exceed those of the predicate device, with a confidence of greater than 95%. The products are equivalent.

7.10. User Evaluation of Device for Cutting and Shaping

The subject device was evaluated in comparison to the predicate for use in the oral environment using a questionnaire. The results showed favorable usability that was substantially equivalent to the predicate for cutting and shaping the device for use as a dental barrier membrane.

7.11.Biocompatibility, Sterilization, Shelf-life and Animal origin.

Testing from the applicant's own predicate device (K190528 and K153364) was used to support substantial equivalence.

Biocompatibility per ISO 10993 series

- Cytotoxicity
- Sensitization
- Irritation or Intracutaneous reactivity
- Acute systemic toxicity
- Subacute/sub-chronic toxicity
- Genotoxicity
- Implantation
- Materials-Mediated Pyrogenicity
- Chronic Toxicity
- Carcinogenicity
- Sterilization validation per ISO 11135, ISO 11737-1, Ethylene Oxide residual test following ISO 10993-7
- Endotoxin validation (<20 EU/device) of sterilization method per LAL turbidimetric kinetic method following ISO 10993-11
- Shelf life per ASTM F1980 and Q5C (R2)[ICH] using accelerated and real-time aged samples
- Packaging per ISO 11607-series, ASTM F88 and ASTM F1886
- Animal Origin and Viral inactivation per ISO 22422 series

The performance data demonstrates that the subject device is substantially equivalent to the predicate device.

8. Performance Testing – Animal

Comparative performance testing in an animal canine (beagle bilateral mandibular bony defect model was used to support equivalence with the predicate device for the stated indications for use. On the 30, 60 and 90 day post-surgery, animal tissues were evaluated for gross pathology and histological, and quantitative micro-CT volumetric analysis of new bone (%) and xenograft (%).

In a side-by-side comparison between the Test (Subject device) and Control (Predicate device), no qualitative or significant differences was observed for new bone formation, xenograft membrane resorption kinetics and soft tissue infiltration. Histologic and micro-CT volumetric analysis revealed no noticeable or significant differences between the two membranes at any time point.

Soft tissue endpoints were part of the applicant's previous canine testing as described in the reference device application K192612.

Studies were performed in AAALC accredited facilities in compliance with the applicable requirements of Good Laboratory Practices (GLP) 21 CFR §58.

9. Performance Testing - Clinical

No human clinical trials were performed in support of this submission.

10. Conclusion

The data provided within this submission support substantial equivalence of the subject device to the predicate device with regards to intended use, materials, design, and technological characteristics, including principles of operation, performance characteristics, and device safety. For use in oral surgical applications, Kerecis Oral is substantially equivalent to the predicate device.