May 2, 2021

Kerecis Limited
Gudmundur Sigurjonsson
CEO
Eyrargata 2 – PO Box 151
Isafjordur, 400
Iceland

Re: K202430
Trade/Device Name: Kerecis Reconstruct
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: OXH
Dated: March 25, 2021
Received: April 1, 2021

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,

Cindy Chowdhury, Ph.D., M.B.A.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K202430

Device Name

Kerecis Reconstruct

Indications for Use *(Describe)*

The subject device is indicated for:

For implantation to reinforce soft tissue where weakness exists, in patients requiring soft tissue repair, or reinforcement in plastic or reconstructive surgery.

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.

Volume 05: 510(k) Summary

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

5.1 Submitter Information

Sponsor Name:	Kerecis Limited
Sponsor Address:	Eyrargata 2 – PO Box 151, 400 Isafjordur, Iceland
Sponsor Telephone:	+354-419-8000
Establishment Registration:	301060025
Contact Person:	Gudmundur Fertram Sigurjonsson
Contact Title:	Chairman
Email Direct:	gfs@kerecis.com
Date Summary Prepared:	March 19, 2021

5.2 Device Information

Trade Name (proprietary):	Kerecis Reconstruct
Common (usual):	Surgical Graft
Device Classification:	Class II, 21 CFR § 878.3300
FDA Device Code:	OXH

5.3 Predicate Device and Reference Devices

Predicate Device

Company Name:	Cook Biotech Inc.
Device Name (proprietary):	Biodesign Plastic Surgery Matrix
Device 510(k):	K191696 (K161221, K034039)

Reference Device #1

Company Name:	Kerecis
Device Name (proprietary):	Kerecis SecureMesh
Device 510(k):	K153364

Reference Device #2

Company Name:	Cook Biotech Inc.
Device Name (proprietary):	Biodesign Hernia Graft
Device 510(k):	K133306

5.4 Device Description

The subject device is a fish skin medical device indicated for physical reinforcement of a soft tissue defect or weakness.

The subject device is obtained from cod fish skin by a standardized controlled manufacturing process and supplied in a peel-pouch terminally sterile packaging in the following rectangular solid sizes:

- 4x7 cm
- 7x10 cm
- 7x20 cm

The subject device is biocompatible, non-crosslinked, and therefore resorbable, strong, flexible, and supports fixation.

5.5 Intended Use

The subject device is indicated for:

- For implantation to reinforce soft tissue where weakness exists, in patients requiring soft tissue repair, or reinforcement in plastic or reconstructive surgery.

5.6 Technological Characteristics

Comparison of the subject device with predicate device (K191696), and the reference devices (K153364 and K133306), demonstrate that it is substantially equivalent with regards to: intended use, materials, design, and operational principle.

5.7 Summary of Supporting Evidence for Substantial Equivalence

- Analysis of 510(k) Substantial Equivalence Decision-Making Process as outlined in FDA's Guidance Document, the 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)].
- Bench testing was performed, following FDA guidance, "Preparation of a Premarket Notification Application for a Surgical Mesh" (1999), including but not limited to: tensile strength, suturability, hydration time test, thickness measurement, weight measurement, stiffness test (bend test), and microscopic structure analysis. All tests were performed on hydrated, sterile, ready-for-market devices, to confirm that the devices perform as expected under clinical conditions, and there were no negative effects on the mechanical properties.

- Animal testing was performed in a GLP laboratory, using the subject/test device and a control device. Based on the results of the study: the veterinarian's assessment of animal health (safety), the pathologist's assessment of the tissue response to the device (safety and efficacy), histology, and the in-vitro performance data tensile strength testing of the test and control explants side-by-side (efficacy), the performance of the subject device showed equivalence in safety and efficacy to that of the control device, when used to reinforce soft tissue defects.

5.8 Summary Table of Substantial Equivalence

A comparison of the subject device, predicate device, and two (2) reference devices are presented in TABLE 5-1.

	Subject Device	Predicate Device	Reference Device	Reference Device	Discussion
Company	Kerecis	Cook Biotech	Kerecis	Cook Biotech	No discussion required
Name	Kerecis Reconstruct	Biodesign Plastic Surgery Matrix	Kerecis SecureMesh	Biodesign Hernia Graft	No discussion required
510(k)	Subject Device	K191696	K153364	K133306	Predicate & Reference devices are all legally marketed in the USA
Device Classification	II	II	II	II	Identical
Regulation	21 CFR 878.3300	21 CFR 878.3300	21 CFR 878.3300	21 CFR 878.3300	Identical
Product Code	OXH	FTM, OXH	OXE	FTM, OXK	Product Code of subject is a subset of the predicate
Intended Use	to reinforce soft tissue where weakness exists in patients requiring soft tissue repair or reinforcement in plastic or reconstructive surgery	to reinforce soft tissue where weakness exists in patients requiring soft tissue repair or reinforcement in plastic or reconstructive surgery	to be used as a staple line buttress	to reinforce soft tissue where weakness exists	Intended Use is identical for the subject & predicate
Indications for Use	Indications for use include soft tissue repair or	Indications for use include soft tissue repair or	Reinforcement of staple lines during:	Indications for use include the repair of hernia	Indications for Use are identical for the subject &

	reinforcement in plastic or reconstructive surgery. The graft is supplied sterile and is intended for one-time use.	reinforcement in plastic or reconstructive surgery. The graft is supplied sterile and is intended for one-time use.	1. Bariatric surgical procedures 2. Gastric, small bowels and mesentery procedures 3. Colorectal and colon procedures 4. Lung and bronchus resections	or body wall defects. The graft is supplied sterile and is intended for one-time use.	predicate (Note: the subject device adds example procedures for clarification)
Material	Atlantic Cod Fish	Porcine	Atlantic Cod Fish	Porcine	Identical material to reference device
Shapes	Rectangular	Rectangular	Custom design for surgical staplers	Rectangular	Subject device is rectangular or shredded. Either configuration is provided sterile in a Tyvek pouch.
Size	4x7 cm 7x10 cm 7x20cm	4x7 cm 7x10 cm 7x20 cm	Multiple sizes for FDA cleared surgical staplers	5x8cm to 30x30cm	Subject device sizes are identical to the predicate device.
Surface Area	Maximum 140cm^2	Maximum 140cm^2	Maximum 600cm^2	Maximum 900cm^2	Subject surface area is within range of SIS devices
Operating Principle	Supports fixation by sutures, tacks, or staples	Supports fixation by sutures, tacks, or staples	Supports fixation by sutures, tacks, or staples	Supports fixation by sutures, tacks, or staples	Identical
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide
Shelf-Life	3 years	1.5 years	3 years	3 years	Identical to reference devices
Requires Re-hydration?	Yes	Yes	Yes	Yes	Identical

5.9 Conclusion

The data provided within this submission support substantial equivalence of the subject device to the predicate device with regards to intended use, technological characteristics including principles of operation, performance characteristics, and device safety.

For use in reinforcement of plastic surgery soft tissue defects, Kerecis Reconstruct is safe, effective, and substantially equivalent to the predicate device.