June 29, 2022

Kerecis Limited
Gudmundur Sigurjonsson
President & CEO
Eyrargata 2
Isafjordur, 400
Iceland

Re: K213231
Trade/Device Name: Kerecis Silicone
Regulatory Class: Unclassified
Product Code: KGN
Dated: September 24, 2021
Received: September 30, 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,

Julie Morabito, Ph.D.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213231

Device Name
Kerecis Silicone

Indications for Use *(Describe)*

Kerecis Silicone is indicated for the management of wounds including:
- Partial and full-thickness wounds
- Pressure ulcers
- Venous ulcers
- Chronic vascular ulcers
- Diabetic ulcers
- Trauma wounds (abrasions, lacerations, partial-thickness burns, skin tears)
- Surgical wounds (donor sites/grafts, post-Mohs surgery, post-laser surgery, podiatric, wound dehiscence)
- Draining Wounds

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 – K213231

1. SUBMITTER/510(K) HOLDER

Kerecis Limited
Eyrargata 2
400 Isafjordur
Iceland
Contact Person: G. Fertram Sigurjonsson
Telephone: 011 354 562 2601

Date Prepared: June 27, 2022

2. DEVICE NAME

Proprietary Name: Kerecis Silicone
Common/Usual Name: Dressing
Wound Collagen
Classification Name: Unclassified
Product code: KGN

3. PREDICATE DEVICES

• Kerecis Marigen Wound Extra	K190528	Predicate Device
• PELNAC™ Bilayer Wound Matrix	K191992	Reference Device

4. DEVICE DESCRIPTION

The subject device is a bilayer of processed resorbable acellular fish dermal matrix adhered to a thin, transparent, porous, soft silicone layer.

The subject device is obtained from fish skin via standardized controlled GMP manufacturing process. The fish dermal matrix layer is approximately 1 mm in thickness and is porous.

The silicone layer is a transparent polyurethane film single-coated with soft, medical grade silicone that is attached to the scaly side of the fish dermal matrix. The silicone layer is porous, soft and conformable to the wound surface.

The subject device is supplied as a sterile intact sheet offered in two configurations: a) with the silicone layer extending beyond the borders of the fish dermal matrix and b) the silicone

layer having the same dimension as the fish dermal matrix with no silicone layer extending beyond the fish dermal matrix.

The silicone acts as: protection for the fish dermal matrix layer, as additional wound coverage, and in configuration (a), as an adhesive contact layer to the skin surrounding the wound.

The silicone layer can be peeled off as the fish dermal matrix is resorbed.

The device is intended for single use only.

5. INTENDED USE

The subject device is indicated for the management of wounds including:

- Partial and full-thickness wounds
- Pressure ulcers,
- Venous ulcers,
- Chronic vascular ulcers,
- Diabetic ulcers,
- Trauma wounds (abrasions, lacerations, partial-thickness burns, skin tears),
- Surgical wounds (donor sites/grafts, post-Mohs surgery, post-laser surgery, podiatric, wound dehiscence),
- Draining wounds

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The subject device and its predicate, Kerecis Marigen Wound Extra (K190528), are both composed of identical, resorbable, acellular fish skin dermal matrix. The fish skin layer is made from wild-caught Atlantic Cod that is minimally processed in order to preserve the natural proteins and structure of the fish skin.

The subject device differs from the predicate device in that it contains a second layer consisting of a porous silicone. The silicone acts to protect the fish dermal matrix layer and is intended to ease the application of the device. The bilayer configuration of the subject device is similar to the reference device PELNAC Bilayer Wound Matrix (K191992) that includes a silicone layer and a porcine-derived collagen matrix layer.

The subject device is substantially equivalent to the predicate device, Kerecis Marigen Wound Extra (K190528).

The following table compares the proposed subject device side-by-side with the predicate device, Kerecis Marigen Wound Extra.

Summary Table of substantial equivalence

Device name	Kerecis Silicone (Subject Device- K213231)	Kerecis Marigen Wound Extra (Primary Predicate- K190528)	Comparison
Manufacturer	Kerecis Limited	Kerecis Limited	N/A
510(k)	K213231	K190528	N/A
Intended for prescription and single use only	Yes	Yes	Same
Product Code	KGN	KGN	Same
Device ClassificationName	Dressing, Wound, Collagen	Dressing, Wound, Collagen	Same
Intended use	Kerecis Silicone is intended for the management of wounds including • Partial and full-thickness wounds • Pressure ulcers • Venous ulcers • Chronic vascular ulcers • Diabetic ulcers • Trauma wounds (abrasions, lacerations, partial-thickness burns, skin tears) • Surgical wounds (donor sites/grafts, post-Mohs surgery, post-laser surgery, podiatric, wound dehiscence) • Draining wounds.	Marigen Wound Extra is indicated for the management of wounds including: • Partial and full-thickness wounds • Pressure ulcers • Venous ulcers • Chronic vascular ulcers • Diabetic ulcers • Trauma wounds (abrasions, lacerations, second-degree burns, skin tears) • Surgical wounds (donor sites/grafts, post-Mohs surgery, post-laser surgery, podiatric, wound dehiscence) • Draining wounds	Same
Materials	Atlantic Cod fish skin + Silicone Film Layer	Atlantic Cod fish skin	Similar
Shape	Sheet (circular and rectangular)	Sheet (circular and rectangular)	Same
Supplied sterile?	Yes	Yes	Same
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Same

	SAL 10^{-6}	SAL 10^{-6}	
Intended for single use?	Yes	Yes	Same
Biocompatibility	Yes	Yes	Same
Dimensions	Circular (diameter): 15mm fish/25mm silicon 20mm 25mm 30mm 35mm Rectangular: 3x7 cm 7x7 cm 7x10cm 7x20cm	Circular (diameter): 15mm 20mm 25mm 30mm 35mm Rectangular: 3x7 cm 7x7 cm 7x10cm 7x20cm	Same
Packaging Configuration	Double Terminal Sterile Tyvek®Pouch	Double Terminal Sterile Tyvek® Pouch	Same
Shelf life	36 months	36 Months	Same

7. PERFORMANCE TESTING

The following table summarizes the tests that have been performed. The tests are either performed on the fish dermal matrix alone (predicate device, MariGen Wound Extra), or on the subject device. The fish dermal matrix is identical in both devices.

Performance tests on the subject device		
Test		Standard
Cytotoxicity	Pass	ISO 10993-5, Biological evaluation of medical devices — Part 5: Tests for *in vitro* cytotoxicity
Sensitization	Pass	ISO 10993-10, Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization
Intracutaneous Irritation	Pass	ISO 10993-10, Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization
Acute Systemic Toxicity	Pass	ISO 10993-11:2017, Biological evaluation of medical devices — Part 11: Tests for systemic toxicity
Material Mediated Pyrogenicity	Pass	ISO 10993-11:2017, Biological evaluation of medical devices — Part 11: Tests for systemic toxicity
Subacute Systemic Toxicity and Implantation Effects	Pass	ISO 10993-6, Biological evaluation of medical devices — Part 6: Tests for local effects after implantation and ISO 10993-11:2017, Biological evaluation of medical devices — Part 11: Tests for systemic toxicity
Endotoxin Validation and Analysis	Pass	ANSI/AAMI ST72 Bacterial Endotoxins - Test Methods, Routine Monitoring, And Alternatives To Batch Testing
Hydration	Pass	N/A
Shelf Life and Stability	Pass	N/A
Tensile strength	Pass	ASTM D638-14 Tensile Properties of Plastics

Additional Performance tests on the Kerecis fish dermal matrix layer alone (leveraged from the predicate device)		
Test		Standard
Implantation	Pass	ISO 10993-6, Biological evaluation of medical devices — Part 6: Tests for local effects after implantation
Genotoxicity	Pass	ISO 10993-3, Biological evaluation of medical devices — Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
Genotoxicity – Chromosomal Aberration	Pass	ISO 10993-3, Biological evaluation of medical devices — Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
Subchronic Toxicity	Pass	ISO 10993-11:2017, Biological evaluation of medical devices — Part 11: Tests for systemic toxicity
Cellular Ingrowth	Pass	N/A
Cell Remains and Collagen Structure	Pass	N/A
Hemostatic Properties	Pass	N/A
Resorption in Sprague-Dawley Rats	Pass	N/A
Collagen Induced Arthritis Mouse Model	Pass	N/A

8. CONCLUSION

Based on the data provided within this submission, the subject device is substantially equivalent to the predicate device in regard to intended use and indication for use, technological characteristics including principles of operation, performance characteristics and device safety.

It is concluded that the subject device is substantially equivalent to the predicate device.