July 10, 2019

Kerecis Limited
Gudmundur Sigurjonsson
CEO
Eyrargata 2
400 Isafjordur, Iceland

Re: K190528
Trade/Device Name: MariGen Wound Extra
Regulatory Class: Unclassified
Product Code: KGN
Dated: March 29, 2019
Received: April 5, 2019

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 Cynthia Chang
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K190528

Device Name
MariGen Wound Extra

Indications for Use *(Describe)*
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 (second degree burn, abrasions, lacerations, 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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510k Summary – K190528

SUBMITTER/510K HOLDER

Company Address:	Kerecis Limited Eyrargata 2 400 Isafjordur Iceland
Contact Person:	Gudmundur Fertram Sigurjonsson Executive Chairman
Telephone:	011 354 562 2601
Date Prepared:	February 20th, 2019

DEVICE NAME

Proprietary Name:	MariGen Wound Extra
Common/Usual Name:	Collagen, Wound, Dressing
Class:	Unclassified
Product code:	KGN

PREDICATE DEVICE

MariGen Wound (K132343), predicate device

SecureMesh (K153364), reference device

DEVICE DESCRIPTION

The subject device is processed fish dermal matrix composed of fish collagen and is supplied as a sterile intact, or meshed sheet ranging in sizes up to 20 x 30 cm. The subject device is obtained from fish skin via standardized controlled GMP manufacturing process and supplied in terminally sterile packaging. The subject device is biocompatible, pliable, and non-cross linked.

The device is intended for single use only.

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, second-degree burns, skin tears)
- Surgical wounds (donor sites/grafts, post-Mohs surgery, post-laser surgery, podiatric, wound dehiscence)
- Draining wounds

TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

MariGen Wound Extra and the predicate device are made of the same material and share the same functional design, principles of operation, and user safety and efficacy. The subject device is substantially equivalent to the legally marketed predicate device with respect to: Indications for use, material composition, device characteristics, manufacturing processes, packaging material, and shelf life. The subject device performs as well as its predicate device and is offered in a greater variety of sizes, including larger sizes. Both devices can be cut to defect size and shape for better fit. In addition, the subject device shares the same safety as the implantable reference device K153364 SecureMesh, which is made of the same fish skin material (the "MariGen Material"). All devices are fully resorbable and do not require a second intervention for removal.

Summary Table of Substantial Equivalence

Device Features	Subject Device: MariGen Wound Extra	Predicate Device: MariGen Wound	SUBSTANTIAL EQUAIVLENCE
510(k) Number	K190528	K132343	
Manufacturer	Kerecis Limited	Kerecis Limited	
Product Codes	KGN	KGN	Equivalent
Intend. Use	Wound Dressing	Wound Dressing	Equivalent
Indications	Management of wounds including: - Partial and full-thickness wounds - Pressure ulcers - Venous ulcers - Chronic vascular ulcers	Management of wounds including: - Partial and full-thickness wounds - Pressure ulcers - Venous ulcers - Chronic vascular ulcers	Equivalent

	- 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	- 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	
Resource origin	Cod Fish skin	Cod Fish skin	Equivalent
Tissue resource / Scaffold base	Identical fish skin tissue	Identical fish skin tissue	Equivalent
Nominal sizes	Sized up to 20 x 30 cm (600 cm^2)	3 x 3.5 cm (10.5 cm^2) 3 x 7 cm (21 cm^2) 7 x 10 cm (70 cm^2)	Equivalent, Subject device has more size variety, incl. larger sizes
Presentation	Solid, fenestrated, or meshed lyophilized skin sheet in a peel pouch	Solid or meshed lyophilized skin sheet in a peel pouch	Equivalent
Sterilization	Ethylene Oxide SAL 10^{-6}, single use only	Ethylene Oxide SAL 10^{-6}, single use only	Equivalent
Shelf life	3 years	3 years	Equivalent

PERFORMANCE DATA

The subject device is a size modified version of the predicate device. Both are made from the MariGen Material. Biocompatibility tests and product characterization studies performed on the predicate device fully apply to the subject device as those are identical materials. Present performance data includes data from: elemental impurities and chemical residual analysis.

The subject device is identical to the predicate device apart from being offered in sizes up to 600cm^2. The subject device does not raise new safety questions for patients. Kerecis's risk-based approach, executed according to EN ISO 14971*: Medical devices - Application of risk management to medical devices,* shows that all sizes of the modified device are safe for use.

The provided data from biocompatibility testing combined with bench testing and animal studies exhibits product safety and effectiveness.

CONCLUSION

The subject device is identical to the predicate device apart from being offered in sizes up to 600cm^2.

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

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