July 16, 2025

Kerecis Limited
Skuli Magnusson
Vice President (Regulatory Affairs, Quality & Clinical Affairs)
Sundastraeti 38, 400 Isafjordur
P.O. Box 151, 400 Isafjordur
Isafjordur, 400
Iceland

Re: K251845
Trade/Device Name: Kerecis® Marigen Wound Extra Autologous Hydration, Kerecis Silicone Autologous Hydration and Kerecis Parvus Autologous Hydration
Regulatory Class: Unclassified
Product Code: KGN
Dated: June 16, 2025
Received: June 16, 2025

Dear Skuli Magnusson:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Mustafa A. Mazher -S

For Yu-Chieh Chiu
Assistant Director
DHT4B: Division of Plastic and
Reconstructive 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)* K251845

Device Name
Kerecis® Marigen Wound Extra Autologous Hydration, Kerecis Silicone Autologous Hydration and Kerecis Parvus Autologous Hydration

Indications for Use *(Describe)*

Kerecis® Marigen Wound Extra Autologous Hydration, Kerecis Silicone Autologous Hydration and Kerecis Parvus Autologous Hydration

Management of wounds including:

· Partial thickness wounds
· 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

☒ 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary – K251845

Premarket Notification Submission (510(k) Summary)

Submitter Information

Sponsor Name:	Kerecis Limited
Sponsor Address:	Eyrargata 2 – PO Box 151, 400 Isafjordur, Iceland
Sponsor Telephone:	+354-419-8000
Establishment Registration:	301060025
Applicant:	Skuli Magnusson,
Title:	VP of Regulatory Affairs, QA & Clinical Affairs
Email Direct:	sm@kerecis.com
Primary Contact Person:	Skuli Magnusson,
Contact Title:	VP of Regulatory Affairs, QA & Clinical Affairs
Email Direct:	sm@kerecis.com
Date Summary Prepared:	July 16, 2025

Device Information

Trade Name (Proprietary):	Kerecis® Marigen Wound Extra Autologous Hydration, Kerecis Silicone Autologous Hydration and Kerecis Parvus Autologous Hydration
FDA Device Code:	KGN
Categorization:	Wound dressing with animal-derived material(s)
Device Class:	Unclassified, (Pre-Amendment)

Primary Predicate Device

Company Name:	Kerecis
Device Name (Proprietary):	Marigen Wound Extra
Device 510(k):	K190528

Additional predicate Devices

Company Name:	Kerecis
Device Name (Proprietary):	Kerecis Silicone
Device 510(k):	K213231

Company Name:	Kerecis
Device Name (Proprietary):	Kerecis Parvus
Device 510(k):	K241080

Device Description

All three subject devices of this bundled submission are part of a family of devices manufactured by Kerecis Limited. The subject devices can be seen in Table 1. They are lyophilized, terminally sterilized, fish skin medical devices comprised of biocompatible, resorbable fish skin (Wild North Atlantic Cod) for wound management. The devices are intended for single use only. The devices are applied to the wound bed to maintain a moist wound environment. The primary predicate device is Marigen Wound Extra (K190528) and the additional predicate devices are Kerecis Silicone (K213231), and Kerecis Parvus (K241080). Marigen Wound Extra is commercially available under the names Kerecis MariGen, Kerecis GraftGuide, and Kerecis SurgiClose. Kerecis Silicone is commercially available under the names Kerecis Shield and Kerecis SurgiClose Silicone. For clarity, this submission will refer to the devices under their commercially available names, except when specifically referring to the primary predicate device. This information is also shown in Table 1.

Table 1: Subject devices of this submission

#	Product Name	510(k) Proprietary Name/Device Name	510(k) Clearance
1	MariGen, GraftGuide, SurgiClose	Marigen Wound Extra	K190528[1]
2	Kerecis Shield Adhesive Kerecis Shield Standard Kerecis Shield Spiral Kerecis SurgiClose Silicone	Kerecis Silicone	K213231
3	Kerecis Parvus	Kerecis Parvus	K241080

Although the subject devices differ from each other in terms of device indications and dimensional specifications, each one remains physically identical to its primary predicate device, both in design and packaging, as well as for indications for use. The only difference between each subject device and its respective primary predicate device is in the device labeling, with the subject devices having additional rehydration fluid options included in their instructions for use (IFUs).

Intended Use / Indications for Use

The intended use of each of the subject devices is listed below. No changes to the intended use are proposed in this bundled 510(k) submission.

Product name(s)	Indications for Use
Kerecis MariGen (K190528), Kerecis GraftGuide	Management of wounds, including: • Partial-thickness wounds

[1] K132343 (Marigen Wound Dressing) was the initial submission covering the products now included in the more recent K190528 submission, which introduced additional size variants.

(K190528), Kerecis SurgiClose (K190528), Kerecis Shield variants (K213231), Kerecis SurgiClose Silicone (K213231), and Kerecis Parvus (K241080).	• 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

Description of Modification

The only modification from the primary predicate device is in the device labeling. The modification that triggered this submission is the inclusion of additional rehydration options in the instructions for use (IFU). In addition to saline (which is the rehydration fluid in the primary predicate devices), lactated Ringer's solution and autologous body fluids are being added as potential rehydration fluid options for the subject devices of this submission.

Kerecis is implementing this modification in response to interest within the field regarding the use of these fluids for device rehydration.

Technological characteristics and substantial Equivalence

The technological characteristics of the subject devices of this submission and the primary predicate devices (K190528, K213231, K241080), are identical to each respective primary predicate device, to that described in their respective submissions in that they are all animal-based products suitable for the management of multiple types of wounds. They also share identical device design and principle of operation, respectively. The following items are provided to demonstrate substantial equivalence to the primary predicate devices:

- Risk analysis summary
- Sterilization justification
- Shelf-life justification
- Biocompatibility justification
- Bench testing

Table 2: Substantial Equivalence comparison table.

Device name	MariGen, GraftGuide, SurgiClose, SurgiClose Silicone, Shield, and Parvus **(Subject Devices)**	Predicate Devices all with the same names as the Subject Devices **(Predicate Devices)**	**Comparison**
Manufacturer	Kerecis Limited	Kerecis Limited	N/A
510(k)	K251845 (Bundled)	K190528 (primary predicate) K213231 (additional predicate) K241080 (additional predicate)	N/A
Prescription, single use only	Yes	Yes	Same
Product Code	KGN (Bundled Submission)	KGN	Same
Indications for Use	The management of wounds including: • Partial-thickness wounds • 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	The management of wounds including: • Partial-thickness wounds • 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	Same
Materials	Atlantic Cod Fish Skin, Atlantic Cod Fish Skin + Silicone Film Layer	Atlantic Cod Fish Skin, Atlantic Cod Fish Skin + Silicone Film Layer	Same
Supplied sterile?	Yes	Yes	Same

Device name	MariGen, GraftGuide, SurgiClose, SurgiClose Silicone, Shield, and Parvus **(Subject Devices)**	Predicate Devices all with the same names as the Subject Devices **(Predicate Devices)**	**Comparison**
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Same
Intended for single use?	Yes	Yes	Same
Rehydration Fluid	<u>All Devices in the bundle:</u> Sterile saline, sterile lactated Ringer's solution and autologous body fluids	<u>All Devices in the bundle:</u> Sterile Saline	Different

Performance Testing

Performance testing for this 510(k) submission was largely leveraged from the Kerecis primary predicate devices, as the subject devices share the same intended use, materials, and manufacturing processes. As a result, additional performance testing was not required, except for rehydration and suture retention tests using autologous body fluid. These specific tests were conducted to address the only modification for the subject devices, i.e., the inclusion of lactated Ringer's solution and of autologous body fluids as rehydration agents. The results confirmed that device performance remains consistent and comparable to the primary predicate devices, supporting a determination of substantial equivalence.

Conclusion

For the purposes of determining substantial equivalence under section 513(i) of the FD&C Act (21 U.S.C. § 360c(i)), the Kerecis® Marigen Wound Extra, Kerecis Silicone, and Kerecis Parvus devices (the subject devices) share the same intended use, functions, mode of action, and fundamental scientific technology as their respective primary predicate devices. Additionally, the subject devices are composed of the same materials and are manufactured using identical processes as the primary predicate devices. The modification is the inclusion of lactated Ringer's solution and of autologous body fluids as optional rehydration fluids in the devices' Instructions for Use (IFUs). Because there are no changes to the fundamental scientific technology or intended use, and verification and validation activities have been completed, there is sufficient evidence to demonstrate that the subject devices perform comparably to the primary predicate devices currently marketed for the same intended use.

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