October 30, 2026

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

Re: K260058
Trade/Device Name: Kerecis® Express (50250)
Regulatory Class: Unclassified
Product Code: KGN
Dated: September 30, 2026
Received: September 30, 2026

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

YU-CHIEH CHIU -S

Yu-Chieh Chiu, Ph. D.
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)*
K260058

Device Name
Kerecis® Express

Indications for Use *(Describe)*
This product 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)
• Tunneled/undermined wounds
• 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.

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

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Prepared in accordance with 21 CFR § 807.92

Submitter Information

Sponsor Name:	Kerecis® Limited
Sponsor Address:	Sundstraeti 38 – PO Box 151, 400 Isafjordur, Iceland
Sponsor Telephone:	+354 4198000
Primary Contact Person:	Skuli Magnusson,
Contact Title:	VP of Regulatory, Quality and Clinical Affairs
Email Direct:	sm@kerecis.com

Date Summary Prepared:	October 23, 2026

Device Information

Trade Name (Proprietary):	Kerecis® Express
Common (Usual):	Collagen Wound Dressing
Classification Name:	Wound dressing with animal-derived material(s)
Device Classification:	Unclassified, (Pre-Amendment)
FDA Device Code:	KGN

Predicate Device

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

Predicate Device

Device Name (Proprietary):	Cook ECM Powder
Device 510(k):	K152033
Company Name:	Cook Biotech Incorporated

Device Description

Kerecis® Express is a lyophilized, terminally sterilized, fragmented fish skin medical device comprised of biocompatible, non-crosslinked, resorbable, acellular fish skin (North Atlantic Cod) for wound management delivered using a single-use syringe. Kerecis Express represents a line extension of the cleared Kerecis Parvus product (K241080). Kerecis Express fish skin fragments are hydrated within its sterile single-use applicator. The applicator delivers the fragments directly into the wound when the plunger is depressed. The hydrated fragments can conform to wound geometries where needed and may provide a

protective, moist environment. Kerecis Express is offered in two configurations: 19 cm^2 (500 mg) and 38 cm^2 (1000 mg).

Indication For Use:

This product 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)
- Tunneled/undermined wounds
- Surgical wounds (donor sites/grafts, post-Mohs surgery, post-laser surgery, podiatric, wound dehiscence)
- Draining wounds

Technological Characteristics and Substantial Equivalence

Kerecis® Express has technological characteristics equivalent to the primary predicate device, Kerecis® Parvus (K241080). Both devices consist of fragmented, non-crosslinked, acellular fish skin derived from North Atlantic cod and are manufactured using the same proprietary processes. The only difference is the method of delivery, as Kerecis® Express is provided in a sterile, single-use prefilled syringe, whereas Parvus is supplied in a pouch. This difference does not alter the device's composition, material properties, or intended function.

Kerecis® Express is also equivalent to the predicate device Cook ECM Powder (K152033), which is indicated for use in tunneled and undermined wounds. Both devices are particulate, resorbable extracellular matrix (ECM)-based wound dressings designed to conform to complex wound geometries, supporting their use in these wound types.

Nonclinical testing, including bench performance, packaging and transportation, biocompatibility, and sterilization/endotoxin testing, was conducted on finished, sterilized devices. All results met predefined acceptance criteria and support that the device performs as intended.

SUBSTANTIAL EQUIVALENCE COMPARISON TABLE

DEVICE	Proposed Device	Predicate Device	Predicate Device	Comparison
Device Name	Kerecis Express	Kerecis Parvus	Cook ECM Powder	N/A
510K Number	K260058	K241080	K152033	N/A
Manufacturer	Kerecis Limited, Iceland	Kerecis Limited, Iceland	Cook Biotech Incorporated	N/A
Device Class	Unclassified	Unclassified	Unclassified	Same
Product Codes	KGN	KGN	KGN	Same as predicate devices.
Intended Use	Management of wounds	Management of wounds	Management of wounds	Same
Indications For Use	• Partial and full-thickness wounds • Pressure ulcers • Venous ulcers • Chronic vascular ulcers • Diabetic ulcers • Trauma wounds (abrasions, lacerations, partial thickness burns, skin tears) • Tunneled/undermined wounds • Surgical wounds (donor sites/grafts, post-Mohs surgery, post-laser surgery, podiatric, wound dehiscence) • Draining wounds	• 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	• Partial and full-thickness wounds • Pressure ulcers • Venous ulcers • Diabetic ulcers • Chronic vascular ulcers • Tunneled/undermined wounds • Surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery podiatric, wound dehiscence) • Trauma wounds (abrasions, lacerations, second-degree burns, and skin tears) • Draining wounds	Same as predicate device (K152033).
Source Origin	Wild Caught Atlantic Cod Fish	Wild Caught Atlantic Cod Fish	Porcine small intestinal submucosa (SIS) that has been processed to isolate the extracellular matrix (ECM)	Same as predicate device (K241080).
Delivery Method	Syringe	Standard	Standard	Different delivery configuration; does not alter the underlying wound-contacting material or

				intended wound-management function..
Nominal sizes	Irregular shaped 3D fragmented fish skin, size controlled to ≤2.00mm and packaged in the following weights: 19 cm^2 (500mg) 38 cm^2 (1000mg)	Irregular shaped 3D fragmented fish skin, size controlled to ≤2.00mm and packaged in the following weights: 4 cm^2 (100mg) 8 cm^2 (200mg) 19 cm^2 (500mg) 38 cm^2 (1000mg) 95 cm^2 (2500mg) 114 cm^2 (3000mg)	Particles ≤1000µm	Same as predicate device (K241080).
Presentation	Supplied sterile in single use syringe for direct administration to the wound in 19 cm^2 (500mg) and 38 cm^2 (1000mg) sizes	Lyophilized, sterilized, Fragmented, fish skin in a Tyvek peel pouch	Lyophilized, sterilized, particles	Addition of syringe to predicate device.
Sterilization	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide	Same as predicate devices
Endotoxin limit	≤20EU/device	≤20EU/device	Not Available	Same as predicate (K241080).
Biocompatibility	Evaluated as a long-term breached or compromised skin-contacting medical device per ISO 10993-1	Evaluated as a prolonged breached or compromised skin-contacting medical device per ISO 10993-1	• Cytotoxicity • Acute systemic toxicity • Irritation/Intracutaneous reactivity *Additional tests unavailable	Same as predicate devices.

Conclusion

Taken together the data provided confirms that the subject device (Kerecis® Express) meets all requirements and is substantially equivalent to the predicate device, Kerecis® Parvus™ (K241080), and Cook ECM Powder (K152033).