August 21, 2024

Kerecis Limited
William Kabitz
Senior Regulatory Specialist
Sundstraeti 38, 400 Isafjordur
P.O. Box 151, 400 Isafjordur
Isafjordur,
Iceland

Re: K241080
Trade/Device Name: Kerecis Parvus (50207)
Regulatory Class: Unclassified
Product Code: KGN
Dated: July 16, 2024
Received: July 22, 2024

Dear William Kabitz:

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.

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K241080

Device Name
Kerecis® Parvus™

Indications for Use *(Describe)*

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

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

Submitter Information

Sponsor Name: Kerecis Limited
Sponsor Address: Eyrargata 2 – PO Box 151, 400 Isafjordur, Iceland
Sponsor Telephone: +354-419-8000

Primary Contact Person: Skuli Magnusson
Contact Title: VP Quality and Regulatory Affairs
Email Direct: sm@kerecis.com

Date Summary Prepared: March 30, 2024

Device Information

Trade Name/Proprietary Name Kerecis® Parvus™
Regulation Number Unclassified
Regulation Name: Wound Dressing With Animal-Derived Material(s)
Product Code: KGN
Classification Unclassified
Panel General & Plastic Surgery

Predicate Device

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

Device Description

Kerecis® Parvus™ is a lyophilized, terminally sterilized, acellular, particulate fish skin medical device comprised of biocompatible, non-crosslinked, resorbable, acellular fish skin (North Atlantic Cod) for wound management. The device is intended for single use only.

The subject device is packaged in the following weights:

100mg (4 cm^2)
200mg (8 cm^2)
500mg (19 cm^2)
1000mg (38 cm^2)
2,500mg (95 cm^2)
3,000mg (114 cm^2)

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

Technological Characteristics & Substantial Equivalence

Comparison with the predicate device (K190528) demonstrates that the subject device is substantially equivalent with regard to indications for use, intended use, raw material origin and composition, device performance, packaging material, and sterilization methods. The manufacturing process adds an additional cutting and sieving step to convert fish skin from intact sheets to fragmented pieces ≤2.0mm.

The subject device is identical to the predicate device with respect to raw material, terminal sterilization, intended use, and indications for use.

Performance Characteristics

DEVICE	Subject Device:	Predicate Device:	Discussion
Device Name	Kerecis® Parvus™	MariGen Wound Extra	N/A
Manufacturer	Kerecis Limited, Iceland	Kerecis Limited, Iceland	Same as predicate
Product Codes	KGN	KGN	Same as predicate
Intended Use	Management of wounds	Management of wounds	Same as predicate
Indications For Use	• Partial and full-thickness wounds • Pressure ulcers • Venous ulcers • Chronic vascular ulcers • Diabetic ulcers • Trauma wounds (abrasions, lacerations, superficial second-degree burns, skin tears) • Surgical wounds (donor sites/grafts, post-Mohs surgery, post-laser surgery,	• Partial and full-thickness wounds • Pressure ulcers • Venous ulcers • Chronic vascular ulcers • Diabetic ulcers • Trauma wounds (abrasions, lacerations, superficial second-degree burns, skin tears) • Surgical wounds (donor sites/grafts, post-Mohs surgery, post-laser surgery,	Same as predicate

	podiatric, wound dehiscence) • Draining wounds	podiatric, wound dehiscence) • Draining wounds	
Source Origin	Wild Caught Atlantic Cod Fish	Wild Caught Atlantic Cod Fish	Same as predicate
Tissue source	Fish Skin	Fish Skin	Same as predicate
Nominal sizes	Irregular shaped 3D fragmented fish skin, size controlled to ≤2.00mm and packaged in the following weights: 100mg (4 cm^2) 200mg (8 cm^2) 500mg (19 cm^2) 1000mg (38 cm^2) 2,500mg (95 cm^2) 3,000mg (114 cm^2)	1.75 x 1.75cm (3.01 cm2) 3 x 3.5 cm (10.5 cm2) 3 x 7 cm (21 cm2) 7 x 7 cm (49 cm2) 7 x 10 cm (70 cm2) 7 x 20 cm (140 cm2) 10 x 20 cm (200 cm2) 20 x 20 cm (400 cm2) 20 x 25 cm (500 cm2) 20 x 30 cm (600 cm2)	The subject device is cut from various predicate device sizes.
Presentation	Lyophilized, sterilized, Fragmented, fish skin in a Tyvek peel pouch.	Lyophilized, sterilized, fish skin sheets in a Tyvek peel pouch.	The predicate and the subject device differ only in the manufacturing steps for cutting and sieving to achieve the finished size of ≤2.00mm.
Packaging	Tyvek Single and Double Peel Pouch	Tyvek Single and Double Peel Pouch	Same as predicate
Sterilization	Ethylene Oxide	Ethylene Oxide	Same as predicate
Sterility Assurance Level	SAL 10^{-6}	SAL 10^{-6}	Same as predicate
Endotoxin limit	≤20EU/device	≤20EU/device	Same as predicate.
Shelf Life	1 year	3 years	Real-time shelf life testing in progress

Performance Data

The subject device is identical to the predicate device with respect to raw material, terminal sterilization, intended use, and indications for use. Additional testing for biocompatibility, fragmented size characterization, endotoxin, shelf life, sterilization, ethylene oxide residuals, metal contamination, protein analysis, bioburden, and residual limits were completed for the subject device.

Conclusion

Taken together the data provided confirms that the subject device (Kerecis® Parvus™) meets all requirements and is substantially equivalent to the predicate device.