June 4, 2025

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

Re: K243843
Trade/Device Name: Tendon Protect (50242)
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: OWY, FTM
Dated: April 28, 2025
Received: April 28, 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,

CHRISTOPHER FERREIRA -S

Christopher Ferreira
Assistant Director
DHT6C: Division of Restorative,
Repair, and Trauma Devices
OHT6: Office of Orthopedic 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.

Submission Number *(if known)*

K243843

Device Name

Tendon Protect (50242)

Indications for Use *(Describe)*

Kerecis Tendon Protect is indicated for the management and protection of tendon injuries in which there has been no substantial loss of tendon tissue.

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."

K243843
Kerecis Tendon Protect 510(k) Summary

Premarket Notification Submission (510(k) Summary)

Submitter Information

Sponsor Name: Kerecis Limited
Sponsor Address: Eyrargata 2 – PO Box 151, 400 Isafjordur, Iceland
Sponsor Telephone: +011 354-419-8000
Establishment Registration: 301060025

Applicant Name and Contact Person: Skuli Magnusson
Title: VP of Regulatory Affairs, QA & Clinical Affairs
Email Direct: sm@kerecis.com

Date Summary Prepared: May 29, 2025

Device Information

Trade Name (Proprietary): Kerecis® Tendon Protect
Common (Usual): Surgical mesh
Classification Name: Mesh, Surgical, Absorbable, Orthopaedics, Reinforcement of Tendon (Primary); Mesh, Surgical
Device Code: OWY (Primary), FTM
Device Classification: Class II
Regulation Number: 21 CFR 878.3300

Primary Predicate Device

Company Name: Integra Lifesciences Corporation
Device Name (Proprietary): Tendon Wrap Tendon Protector
Device 510(k): K053655

Additional Predicate Device

Company Name: Kerecis Limited
Device Name (Proprietary): Kerecis® Reconstruct™
Device 510(k): K202430

Reference Device

Company Name: Kerecis Limited
Device Name (Proprietary): MariGen Wound Dressing
Device 510(k): K132343

Device Description

Kerecis® Tendon Protect is a medical device made from solid fish skin (North Atlantic Cod) sheets of thickness no less than 0.4 mm. The product is intended to provide a covering around the newly repaired tendon for the management and protection of tendon injuries in which there has been no substantial loss of tissue. The device with natural structure and proteins from fish skin is applied around the newly repaired tendon. The structure of the fish skin provides a supportive environment for new host tissue deposition as part of wound healing while still providing an initial barrier facilitating the sliding of the repaired tendon within the surrounding tissue during tendon use. The biomechanical strength for the tendon itself is provided separately by sutures used to repair the tendon tear and/or by sutures or bone anchors used to attach the tendon tissue to the bone.

The fish skin is fully integrated into the surrounding tissue over time, with corresponding new host tissue deposition. The device is biocompatible, non-crosslinked, bioresorbable, strong, and pliable. Its tensile strength supports fixation by sutures customary for tendon protection surgical procedures. The device is intended for one-time use and supplied sterile in labelled Tyvek® pouch packaging.

The subject device is available in following sizes

- 3x5 cm size
- 6x9 cm size

Kerecis® Tendon Protect is a standalone, single use medical device made from fish skin that is technologically similar to the predicate device Tendon Wrap Tendon Protector (K053655) (Substantial Equivalence) and identical to the Kerecis® Reconstruct™ (K202430).

Intended Use / Indication For Use

Kerecis® Tendon Protect™ is indicated for the management and protection of tendon injuries in which there has been no substantial loss of tendon tissue.

Technological Characteristics

Kerecis® Tendon Protect™ and its predicates are discussed in the table below.

	Tendon Protect (subject device)	**Tendon Wrap Tendon Protector (primary predicate device)**	**Kerecis Reconstruct (additional predicate device**	**Discussion**
Manufacturer	Kerecis	Integra Life Sciences	Kerecis	No discussion necessary
510k number	K243843	K053655	K202430	No discussion necessary
Indications for use	Kerecis® Tendon Protect™ is indicated for the management and protection of tendon injuries in which there has been no substantial loss of tendon tissue.	Tendon Wrap Tendon Protector is indicated for the management and protection of tendon injuries in which there has been no substantial loss of tendon tissue.	For implantation to reinforce soft tissue where weakness exists, in patients requiring soft tissue repair, or reinforcement in plastic or reconstructive surgery.	Identical to primary predicate

Material source/ Chemical composition	Fish skin (North Atlantic Cod)	Bovine / Porous matrix of cross-linked bovine Type I collagen and glycosaminoglycan	Fish skin (North Atlantic Cod)	Identical to additional predicate
Design	Solid rectangles	Solid rectangles	Solid rectangles	Identical to primary and additional predicate
Sterilization	Terminally sterilized	Terminally sterilized	Terminally sterilized	Identical to primary and additional predicate
Shelf life	3 years	2 years	3 years	Identical to additional predicate
Dimensions	3 x 5 cm 6 x 9 cm	5 x 5 cm 10 x 12.5 cm	4x7 cm 7x10 cm 7x20 cm	Size range similar to the primary and additional predicate

Non-Clinical Performance Testing

The Kerecis Tendon Protect device was subjected to a range of biological and physical tests demonstrating physical and tensile characteristics. All of the tests below were conducted and passed successfully according to the test specifications:

Biocompatibility Testing:

- Cytotoxicity (ISO 10993-5)
- Sensitization (10993-10)
- Irritation or intracutaneous reactivity (ISO 10993-10)
- Material mediated pyrogenicity (ISO 10993-11)
- Implantation Effects (ISO 10993-6)
- Genotoxicity (ISO 10993-3)
- Acute systemic toxicity (ISO 10993-11)
- Subacute/subchronic toxicity (ISO 10993-11)

Bench Testing:

- **Tendon Summative Usability Evaluation.** As part of the product development process, the Kerecis Tendon product was subjected to usability engineering activities to evaluate its safety and effectiveness as a medical device per ISO 62366-2. Through these activities and analyses, it was determined that the Kerecis Tendon product is safe and effective for use as it met all the pre-defined acceptance criteria (detailed below).

- To support the performance requirements of a surgical mesh, testing was completed per FDA Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh. Ball burst testing, suture retention testing and tensile strength testing was performed. The results met the

acceptance criteria.

Animal Testing:
Tendon GLP Chicken Study.
Testing was performed to evaluate the Kerecis Tendon Protect in a chronic chicken flexor tendon model that evaluated an early, mid-term and late time point corresponding to collagen mesh materials. The performance of the subject device was compared to both a control (K053655) and a negative control (sham surgery group). The primary and secondary endpoints included histopathology evaluation, macroscopic evaluations, tendon biomechanical function assessment and overall animal health and the study demonstrated that acceptance criteria were met. The testing demonstrated that the subject device, with different technological characteristics (fish skin derived), exhibited similar overall performance to the marketed predicate device in terms of tendon healing.

Conclusion

Kerecis® Tendon Protect is safe and effective under the proposed conditions of use, and substantially equivalent to its predicate devices. Kerecis® Tendon Protect has similar composition, indications for use, intended use, and technological characteristics as compared to the predicate device. The predicate device Integra Tendon Wrap device (K053655) has been legally marketed, in sizes from 2-inch x 2-inch to 5 inch and has been well-received in the wound management market. There are no significant differences in the safety and effectiveness between the subject device and the predicate device. Safety and efficacy are supported through usability testing, animal testing, biocompatibility, and physical properties tested.