DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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August 19, 2016

Kerecis Limited
Gudmundur Sigurjonsson
CEO
Eyrargata 2
Isafjordur, 400 Iceland

Re: K153364
Trade/Device Name: Kerecis SecureMesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: OXE
Dated: July 15, 2016
Received: July 21, 2016

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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)*
K153364

Device Name

Kerecis SecureMesh

Indications for Use *(Describe)*

Kerecis SecureMesh is intended for use as a prosthesis when staple line reinforcement is needed in surgical repair of soft tissue deficiencies using surgical staplers.
Kerecis SecureMesh can be used for reinforcement of staple lines during:
- Bariatric surgical procedures
- Colorectal and Colon surgical procedures
- Gastric, small bowels and mesentery procedures
- Lung and bronchus resections

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.

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510k Summary

1 SUBMITTER/510K HOLDER

Address:	Kerecis Limited
	Eyrargata 2
	400 Isafjordur
	Iceland
Contact Person:	Gudmundur Fertram Sigurjonsson
	Executive Chairman
Telephone:	011 354 562 2601
Date Prepared:	November 9th, 2015

2 DEVICE NAME

Proprietary Name:	Kerecis SecureMesh
Common/Usual Name:	Surgical Mesh
Classification Name:	Mesh, Surgical
Classification Product Code:	OXE
Regulatory Number:	878.3300

3 PREDICATE DEVICES

- Veritas Dry Collagen Matrix (K041669)- Primary Predicate
- MariGen Wound (K132343) - Supporting Predicate

4 DEVICE DESCRIPTION

Subject Device is formed of intact acellular fish skin and is intended to be used as a staple line buttress with surgical staplers. The buttress material is supplied in a double pouch sterile packaging (EtO), where a pair of buttresses is provided on a pair of carriers to be used by a healthcare professional, to transfer the buttresses to the opposed jaws of a surgical stapler in the operating theatre prior to a stapling procedure. One pair of carrier and a buttress is used for each stapler firing.

5 INTENDED USE

Subject Device is intended for use as a prosthesis when staple line reinforcement is needed in surgical repair of soft tissue deficiencies using surgical staplers.

Subject Device can be used for reinforcement of staple lines during:

- Bariatric surgical procedures
- Colo-rectal and colon surgical procedures
- Gastric, small bowels and mesentery procedures
- Lung, and bronchus resections

6 COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

Subject Device is substantially equivalent to the Primary Predicate, where the intended use and indication list of the Subject Device falls within the intended use and indication list of the Primary Predicate.

The Subject Device, and the Supporting Predicate, both are fish skin sheets that have been decellularized and lyophilized. Both devices consist of a terminally sterilized sheet of the processed fish skin provided in prescribed size configuration and thicknesses. Both are packaged in a pouch configuration.

510(k)	Subject Device K153364	Primary Predicate (K041669)
Device name	Kerecis SecureMesh	Veritas Dry Collagen Matrix
Product Codes	OXE	FTM
Intended use	Intended to be used as a staple line buttress	Intended to be used as a staple line buttress
Indications	Reinforcement of staple lines during	Reinforcement of staple lines during
1	Bariatric surgical procedures	Bariatric surgical procedures

2	Gastric, small bowels and mesentery procedures	Gastric, small bowel, mesentery
3	Colorectal and colon procedures	Colon and colorectal procedures
4	Lung, and bronchus resections	Lung and bronchus resections
5	Not claimed	Occlusion of the left atrial appendage during open chest procedures during cardiac
Animal Origin	Atlantic Cod Fish	Bovine
Tissue type	Skin	Pericardium
Presentation	A delivery system with an absorbable buttress (dehydrated, non-cross- linked	A delivery system with a buttress (comprised of dehydrated, non-cross- linked

Table 1 Comparing the predicate device and subject device Intended Use and Indication for Use. The devices share the underlying functional design and principles of operation

7 PERFORMANCE

7.1 BENCH TESTING

The Supporting Predicate, MariGen Wound (K132343) has undergone appropriate biocompatibility testing and viral-inactivation evaluation. The information provided demonstrate that the device is biocompatible and that viral risks are not present. The Subject Device, (K153364) and the Supporting Predicate, MariGen Wound (K132343) utilize the same raw materials (fish skin), processing components/solutions and manufacturing processes, and are identical. Therefore, no further biocompatibility testing or anti-viral considerations were made.

The Subject Device is substantially equivalent to the Primary Predicate in terms of physical characteristics and tests results. The following tests have been performed to substantiate the equivalence.

510(k)	Subject Device K153364
Device name	Kerecis SecureMesh
Tensile strength	A Uniaxial strength test was performed to compare the tensile strength of the product and the predicate

Usability	Loading time, Transfer of buttress to stapler, Ease of Use, Force to fire and Slippage
Performance	Leak at Staple line, Leak Pressure and Seal burst

Table 2 - Subject Device Bench testing

7.2 ANIMAL STUDIES

An acute porcine ex-vivo study was performed on the Subject Device and Peri-Strips Dry Staple Line Reinforcement (K040415) to support substantial equivalence. Peri-Strips Dry Staple Line Reinforcement (K040415) is the Predicate Device for the Veritas Dry Collagen Matrix (K041669) and the two materials are identical, from the material source, with the same treatment indications as well as mechanical and clinical properties. Comparison with un-buttressed stapling was also undertaken (negative control).

There was no significant difference between the Subject Device and the Primary Predicate. The Subject Device technological and physical characteristics are equivalent to the Predicate Device.

7.3 CLINICAL STUDIES

No clinical testing was included in this submission

8 CONCLUSION

The subject device, Kerecis SecureMesh, meets the requirements to perform its intended use as a staple line sealer and is substantially equivalent to the legally marketed predicate device, Veritas Dry Collagen Matrix (K041669).