

510k Summary

1 SUBMITTER/510K HOLDER

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Executive Chairman

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Date Prepared: October 1, 2013

OCT 23 2013

2 DEVICE NAME

Proprietary Name: MariGen Wound Dressing

Common/Usual Name: MariGen Wound

Classification Name: Collagen Wound Dressing

510k Number: K132343

3 PREDICATE DEVICES

- Mesynthes Endoform™ Dermal Template (K092096)
- ACell MatriStem™ (K092926)
- Integra™ Wound Matrix (Integra Life Sciences) (K021792)
- LifeCell Corporation's LTM Wound Dressing (K082103)
- TEI Biosciences Inc. PriMatrix (K083440)
- HemCon Chitoflex Surgical Dressing (K071519)
- Cook Biotech, Oasis (K061711)

4 DEVICE DESCRIPTION

The Kerecis MariGen Wound Dressing is processed fish dermal matrix composed of fish collagen and is supplied as a sterile intact, or meshed sheet ranging in size from 3 x 3.5 cm (10.5 cm²), 3 x 7 cm (21 cm²) and 7 x 10 cm (70 cm²).

The device is intended for a single patient, one time use only.

5 INTENDED USE

MariGen Wound 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, second-degree burns, skin tears)
- Surgical wounds (donor sites/grafts, post-Mohs surgery, post-laser surgery, podiatric, wound dehiscence).
- Draining wounds

6 TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The Kerecis MariGen Wound Dressing is substantially equivalent to the predicate devices with respect to material composition, device characteristics and intended use.

7 MECHANICAL TESTS AND BIOCOMPATIBILITY TESTS

The Kerecis MariGen Wound Dressing has been subjected to extensive testing to assess the biocompatibility and the performance of the device. The Kerecis MariGen Wound Dressing was shown to be usable and biocompatible.

All biocompatibility tests that are required according to ISO 10993-12 "Biological Evaluation of Medical Devices" were performed with favorable results. Tests were done in the following categories; cytotoxicity, sensitization, irritation, subchronic toxicity and genotoxicity.

8 ANIMAL TESTING

Several animal studies have been performed on the device.

The results of the tests support the safety of the device.

9 CLINICAL TESTING

MariGen Wound is CE marked and has been in commercial use since 2011

The product has been studied on a limited number of subjects and this use supports the safety of the device. No serious adverse events have been noted in limited clinical use.

10 CONCLUSIONS

The proposed and predicate devices have the same general intended use and principles of operation. The overall design of the proposed and predicate devices is similar in that they are all comprised of collagen. The differences between these devices are limited to the animal source of collagen. This difference is minor and does not raise new issues of safety or effectiveness.

The MariGen Wound Dressing meets all defined acceptance criteria for the non-clinical testing required by the risk analysis. The design validation activities confirmed that the device as designed functions to meet specified user requirements. The information provided confirms that the MariGen Wound Dressing device is safe and effective for its intended use and performs as intended.



Kerecis LTD.
Gudmundur F. Sigurjonsson
Executive Chairman
Eyrargata 2
400 Isafjordur
Iceland

October 23, 2013

Re: K132343
Trade/Device Name: MeriGen Wound Dressing
Regulatory Class: Unclassified
Product Code: KGN
Dated: July 19, 2013
Received: August 7, 2013

Dear 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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

Mark N. Melkerson -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K132343

Device Name
MariGen Wound Dressing

Indications for Use (Describe)

MariGen Wound Dressing 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, second-degree burns, skin tears)
- Surgical wounds (donor sites/grafts, post-Mohs surgery, post-laser surgery, podiatric, wound dehiscence), and
- 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

David Krause -S