November 21, 2022

Reprise Biomedical
% Kathy Herzog
Sr. Regulatory, Quality, and Compliance Consultant
DuVal & Associates, P.A.
825 Nicollet Mall, Suite 1820
Minneapolis, Minnesota 55402

Re: K223257
Trade/Device Name: Miro3D Wound Matrix
Regulatory Class: Not Classified
Product Code: KGN
Dated: October 21, 2022
Received: October 21, 2022

Dear Kathy Herzog:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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,

Julie A. Morabito -S

Julie Morabito, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic 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)*
K223257

Device Name
Miro3D Wound Matrix

Indications for Use *(Describe)*
The Miro3D Wound Matrix is indicated for the following:

The Miro3D Wound Matrix is intended for the management of wounds including:
- Partial and full thickness wounds
- Pressure ulcers
- Venous ulcers
- Chronic vascular ulcers
- Diabetic ulcers
- Tunneled, undermined wounds
- Trauma wounds (abrasions, lacerations, partial thickness burns, and skin tears)
- Draining wounds
- Surgical wounds (donor sites/grafts, post-Mohs' surgery, post-laser surgery, podiatric, wound dehiscence)

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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K223257

510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR §807.92:

I. SUBMITTER

Reprise Biomedical, Inc.
17400 Medina Road, Suite 100
Plymouth, MN 55447

Contact Person: Carrie Powers
763-284-6780
cpowers@reprisebio.com

Date Prepared: November 17, 2022

II. DEVICE

Trade/Proprietary Names:	Miro3D Wound Matrix
Common Name:	Animal-derived, extracellular matrix wound care product
Regulation Number:	Unclassified
Regulation Name:	NA
Device Class:	Unclassified
Product Code:	KGN
Panel:	General & Plastic Surgery

III. PREDICATE DEVICE

Miro3D Wound Matrix, K221520
This predicate has not been subject to a design-related recall.
No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

The Reprise Miro3D Wound Matrix is a sterile, single use, non-crosslinked acellular wound dressing that is derived from porcine liver tissue. The liver is perfusion decellularized resulting in a collagen matrix that is dried and cut to defined sizes. The Miro3D porous scaffold provides a protective environment for wound healing. The

device is packaged dry, terminally sterilized in its packaging by e-beam irradiation and is rehydrated with sterile saline or lactated Ringer's solution prior to use. The Miro3D Wound Matrix is provided in four sizes that may be cut to fit a wound size prior to application.

V. INDICATIONS FOR USE

The Miro3D Wound Matrix is indicated for the following:

The Miro3D Wound Matrix is intended for the management of wounds including:

- Partial and full thickness wounds
- Pressure ulcers
- Venous ulcers
- Chronic vascular ulcers
- Diabetic ulcers
- Tunneled, undermined wounds
- Trauma wounds (abrasions, lacerations, partial thickness burns, and skin tears)
- Draining wounds
- Surgical wounds (donor sites/grafts, post-Mohs' surgery, post-laser surgery, podiatric, wound dehiscence)

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The subject and predicate Miro3D Wound Matrix are identical product. The only difference is the labeling for the subject device includes MR Safe information and symbols. This modification does not change the intended use or the technological characteristics of the device.

Table 1: Subject Miro3D vs. Predicate MiroDerm

Feature	Miro3D Wound Matrix (Subject Device)	MiroDerm Wound Matrix (Predicate Device)
K Number	K223257	K221520
Classification	Unclassified (pre-amendment)	Unclassified (pre-amendment)
Product Code	KGN	KGN
Class	II	II
Intended Use	Wound management	Wound management
Indications For Use	The Miro3D Wound Matrix is intended for the management of wounds including:	The Miro3D is intended for the management of wounds including: • Partial and full thickness wounds

Feature	Miro3D Wound Matrix (Subject Device)	MiroDerm Wound Matrix (Predicate Device)
	• Partial and full thickness wounds • Pressure ulcers • Venous ulcers • Chronic vascular ulcers • Diabetic ulcers • Tunneled, undermined wounds • Trauma wounds (abrasions, lacerations, partial thickness burns, and skin tears) • Draining wounds • Surgical wounds (donor sites/grafts, post-Mohs' surgery, post-laser surgery, podiatric, wound dehiscence)	• Pressure ulcers • Venous ulcers • Chronic vascular ulcers • Diabetic ulcers • Tunneled, undermined wounds • Trauma wounds (abrasions, lacerations, second-degree burns, and skin tears) • Draining wounds • Surgical wounds (donor sites/grafts, post-Mohs' surgery, post-laser surgery, podiatric, wound dehiscence)
Type of Use	Wound management	Wound management
User	Physician or other clinician trained in wound care	Physician or other clinician trained in wound care
Intended Use Environment	Surgical suite, hospital, ambulatory surgery center or out-patient clinic	Surgical suite, hospital, ambulatory surgery center or out-patient clinic
Description	Animal-sourced, non-crosslinked, acellular collagen tissue matrix	Animal-sourced, non-crosslinked, acellular collagen tissue matrix
Principle of Operation	Provide a protective environment for wound healing	Provide a protective environment for wound healing
Material	Perfusion-decellularized porcine liver	Perfusion-decellularized porcine liver
Resorbable	Yes	Yes
Configuration	Three-dimensional collagen scaffold provided in four sizes (W x L), all 2 cm thickness (Model Number) • 2 cm x 2 cm (3000) • 3 cm x 3 cm (3005) • 5 cm x 5 cm (3010) • 10 cm x 5 cm (3015)	Three-dimensional collagen scaffold provided in four sizes (W x L), all 2 cm thickness (Model Number) • 2 cm x 2 cm (3000) • 3 cm x 3 cm (3005) • 5 cm x 5 cm (3010) • 10 cm x 5 cm (3015)
Wound Matrix Preparation	Rehydrate a minimum of five minutes in either sterile saline or lactated Ringer's solution; cut/trim the wound matrix to fit wound	Rehydrate a minimum of five minutes in either sterile saline or lactated Ringer's solution; cut/trim the wound matrix to fit wound

Feature	Miro3D Wound Matrix (Subject Device)	MiroDerm Wound Matrix (Predicate Device)
Single Use or Reusable	Single Use	Single Use
Sterilization Method	Electron beam irradiation	Electron beam irradiation
Sterilization Assurance Level (SAL)	10^{-6}	10^{-6}
Packaging	• **Device package**: Packaged dry in a PETG plastic tray and snap-on lid with Tyvek lid seal • **Sterile barrier:** Aluminum laminate foil pouch • **Shelf box:** Cardboard	• **Device package**: Packaged dry in a PETG plastic tray and snap-on lid with Tyvek lid seal • **Sterile barrier:** Aluminum laminate foil pouch • **Shelf box:** Cardboard
MR Compatibility	MR Safe	MR Not Evaluated
Shelf Life	25 months (as of this submission date; real-time aging will continue to support 3-year shelf life)	25-months based on real-time aging test results (was 18 months at the time of K221520 submission)
Storage Conditions	No special storage conditions required	No special storage conditions required

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination:

1. MR Testing was completed in compliance with the following FDA-recognized consensus standards:
   - ASTM F2119-07 (Reapproved 2013): Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants
   - ASTM F2052-21: Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment
   - ASTM F2213-17: Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment
   - ASTM F2182-19e2: Standard Test Method for Measurement of Radio Frequency Induced Heating on or Near Passive Implants During Magnetic Resonance Imaging
   - ASTM F2503-20: Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment

Shelf-life/stability, performance testing, and biocompatibility end points evaluation were leveraged from the predicate device since there is no change in the materials and manufacturing processes except the addition of MR safe labeling.

VIII. CONCLUSIONS

The subject Miro3D Wound Matrix has the same intended use as the predicate Miro3D Wound Matrix to provide a protective environment for wound healing. The subject and predicate devices are the same product and thus have the same technological characteristics as the modification to labeling to add MR Safe language and symbols does not change the intended use, indications for use, or technological characteristics of the device. Performance testing provides evidence the Miro3D device is MR Safe. Therefore, the subject device, Miro3D Wound Matrix is as safe, and as effective, as the predicate Miro3D Wound Matrix (K221520).