August 25, 2022

Reprise Biomedical, Inc.
Kathy Herzog
Regulatory Consultant
17400 Medina Road Suite 100
Plymouth, Minnesota 55447

Re: K221520
Trade/Device Name: Miro3D Wound Matrix
Regulatory Class: Not Classified
Product Code: KGN

Dear Kathy Herzog:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated August 18, 2022. Specifically, FDA is updating this SE Letter as an administrative correction to include the 510k Summary document for K221520, as it was inadvertently excluded from our August 18, 2022 SE Letter.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Julie Morabito, OHT4: Office of Surgical and Infection Control Devices, 240-247-6328 or at julie.morabito@fda.hhs.gov.

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

August 18, 2022

Reprise Biomedical, Inc.
Kathy Herzog
Regulatory Consultant
17400 Medina Road Suite 100
Plymouth, Minnesota 55447

Re: K221520
Trade/Device Name: Miro3D Wound Matrix
Regulatory Class: Not Classified
Product Code: KGN
Dated: May 24, 2022
Received: May 25, 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 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)*
K221520

Device Name
Miro3D Wound Matrix

Indications for Use *(Describe)*

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, 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 *(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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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."

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
763-284-6795

Contact Person: Carrie Powers
Date Prepared: August 18, 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

MiroDerm Wound Matrix (also known as Miromatrix Wound Matrix), K140510
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, second-degree 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 Miro3D Wound Matrix is the dry, uncompressed version of MiroDerm which is supplied as a wet, compressed flat sheet. The subject and predicate devices have the same technological characteristics as the change in configuration does not change the Intended Use or fundamental scientific technology of the collagen matrix for wound management. No new device materials or manufacturing materials are introduced with the Miro3D as compared to MiroDerm. The devices have the same material/chemical composition, principle of operation, clinical use, biocompatibility, and sterilization. The device packaging materials for Miro3D (PETG and Tyvek) are commonly used in the medical device industry with a long history of safe use.

Table 1: Subject vs. Predicate Wound Matrix Comparison

Feature	Miro3D Wound Matrix (Subject Device)	MiroDerm Wound Matrix (Predicate Device)
K Number	K221520	K140510
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 Miromatrix Wound Matrix is intended for the management of wounds including:

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, second-degree burns, and skin tears) • Draining wounds • Surgical wounds (donor sites/grafts, post-Mohs' surgery, post-laser surgery, podiatric, wound dehiscence)	• Partial and full thickness wounds • 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)	Flat collagen sheet provided in nine sizes (W x L), thickness ranging from 0.3 to 1.5 mm (Model Number): • 2 cm x 2 cm (BLM-200-02-0202) • 2 cm x 3 cm (BLM-200-02-0203) • 3 cm x 3 cm (BLM-200-02-0303)

Feature	Miro3D Wound Matrix (Subject Device)	MiroDerm Wound Matrix (Predicate Device)
		• 4 cm x 4 cm (BLM-200-02-0404) • 3 cm x 7 cm (BLM-200-02-0307) • 5 cm x 5 cm (BLM-200-02-0505) • 8 cm x 8 cm (BLM-200-02-0808) • 7 cm x 10 cm (BLM-200-02-0710) • 8 cm x 15 cm (BLM-200-02-0815)
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	Soak for two minutes in either sterile saline or lactated Ringer's solution; cut/trim wound matrix to fit wound
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 wet in an aluminum laminate foil pouch • **Sterile barrier**: Aluminum laminate foil pouch • **Shelf box**: Cardboard
Shelf Life	18 months (as of this submission date; real-time aging will continue to support 3 year shelf life)	3 years
Storage Conditions	No special storage conditions required	No special storage conditions required
Biocompatibility	Biocompatibility testing or justification for all applicable	Biocompatibility testing or justification for all applicable

Feature	Miro3D Wound Matrix (Subject Device)	MiroDerm Wound Matrix (Predicate Device)
	biological endpoints per ISO 10993-1:2018 were completed	biological endpoints per ISO 10993-1:2009 were completed
Viral Inactivation	Manufacturing process is capable of inactivating four viruses	Manufacturing process is capable of inactivating four viruses
Bench Testing	The following tests were conducted: • Residual DNA • Collagen analysis • Endotoxin • Expiration dating • Residual detergent • Dimensions • Rehydration	The following tests were conducted: • Residual DNA • Collagen analysis • Endotoxin • Expiration dating • Residual detergent
Animal Wound Healing Study	GLP Study to evaluate Miro3D compared to MiroDerm as a control article in a porcine full thickness wound healing model	None completed

VII. PERFORMANCE DATA

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

1. **Biocompatibility Testing**
   a. Cytotoxicity, ISO 10993-5:2009
   b. Sensitization, ISO 10993-10:2010
   c. Intracutaneous Reactivity, ISO 10993-10:2010
   d. Acute Systemic Toxicity, ISO 10993-11: 2017
   e. Material Mediated Pyrogenicity, ISO 10993-11:2017
   f. Implantation, ISO 10993-6:2016
   g. Subacute Systemic Toxicity, ISO 10993-11:2017
   h. Subchronic Systemic Toxicity, ISO 10993-11:2017
   i. Genotoxicity (Ames Bacterial Reverse Mutation and Mouse Lymphoma), ISO 10993-3:2014

2. **Bench Testing**
    a. **Package Stability Testing**, ASTM F988-09, ASTM F2096, ISO 11607-1:2019, ASTM F2825-18, ASTM D4169-16, and ASTM F2096-11
    b. **Product Testing**
        1. Collagen denaturation temperature, ASTM D3418
        2. Mechanical testing – Dimensional
        3. Rehydration
        4. Residual detergent
        5. Residual DNA
        6. Bacterial endotoxin testing, ST72:2019
        7. Viral inactivation

In addition, Reprise Biomedical sponsored a GLP compliant animal study to evaluate Miro3D compared to MiroDerm on healing of porcine full thickness wounds. The study results indicated that Miro3D performed comparably to MiroDerm in all aspects evaluated.

MR compatibility was not evaluated.

VIII. CONCLUSIONS

The subject Miro3D Wound Matrix has the same Intended Use as the predicate MiroDerm Wound Matrix to provide a protective environment for wound healing. The subject and predicate devices have the same technological characteristics as the change in configuration (dry, uncompressed for Miro3D and wet, compressed for MiroDerm) does not change the Intended Use, chemical composition, or fundamental scientific technology of the collagen matrix for wound management. The Miro3D device packaging materials are common in the industry and do not introduce any new hazards. These modifications in configuration and device packaging materials do not raise different questions of safety and effectiveness compared to the predicate device. Performance testing provides evidence the Miro3D device performs as intended and is as safe and effective as the predicate device. Therefore, the subject Miro3D device is substantially equivalent to the predicate MiroDerm device (K140510).