March 1, 2024

Reprise Biomedical, Inc.
℅ Kathy Herzog
Sr. Regulatory, Quality, and Compliance Consultant
DuVal & Associates
1820 Medical Arts Building, Suite 1820
Minneapolis, Minnesota 55402

Re: K240277
Trade/Device Name: MiroDry Wound Matrix
Regulatory Class: Unclassified
Product Code: KGN
Dated: January 31, 2024
Received: January 31, 2024

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 (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.

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,

Yu-chieh Chiu -S

Yu-Chieh Chiu, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic and Reconstructive 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)*
K240277

Device Name
MiroDry Wound Matrix

Indications for Use *(Describe)*
The MiroDry 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.

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."

510(k) Summary

This 510(k) summary is prepared 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: Erin Badali, Regulatory Affairs Product Specialist
Date Prepared: January 31, 2024

II. DEVICE

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

III. PREDICATE DEVICE

Miro3D Wound Matrix (K223257).
This predicate has not been subject to a design-related recall.
No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

The MiroDry 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 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 MiroDry Wound Matrix is provided in six sizes that may be cut to fit a wound size prior to application.

V. INDICATIONS FOR USE

The MiroDry Wound Matrix is indicated for the following:

The MiroDry 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 devices have the same technological characteristics as the change to a thinner thickness and additional rectangular sizes 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 MiroDry as compared to Miro3D. The subject and predicate devices have identical intended use, Indications for Use, material/chemical composition, principles of operation, clinical use, manufacturing process, biocompatibility, packaging, and sterilization.

Table 1: Subject vs. Predicate Wound Matrix Comparison

Feature	MiroDry Wound Matrix (Subject Device)	Miro3D Wound Matrix (Predicate Device) K223257
Classification	Unclassified (pre-amendment)	Unclassified (pre-amendment)
Product Code	KGN	KGN
Intended Use	Wound management	Wound management
Indications For Use	The MiroDry Wound Matrix is intended for the management of wounds including: • Partial and full thickness wounds • Pressure ulcers • Venous ulcers • Chronic vascular ulcers • Diabetic ulcers	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

Feature	MiroDry Wound Matrix (Subject Device)	Miro3D Wound Matrix (Predicate Device) K223257
	• 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)	• 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)
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
Material	Perfusion-decellularized porcine liver	Perfusion-decellularized porcine liver
Resorbable	Yes	Yes
Manufacturing process	• Perfusion decellularize porcine liver • Dry • Cut to size	• Perfusion decellularize porcine liver • Dry • Cut to size
Wound Matrix Configuration and Sizes	Collagen sheet scaffold provided in six sizes (W x L), all 0.6cm thick (Model Number) • 2cm x 2cm (6000) • 3cm x 3cm (6005) • 4cm x 4cm (6010) • 5cm x 5cm (6015) • 10cm x 3cm (6020) • 10cm x 5cm (6025)	Three-dimensional collagen scaffold provided in four sizes (W x L), all 2cm thick (Model Number) • 2cm x 2cm (3000) • 3cm x 3cm (3005) • 5cm x 5cm (3010) • 10cm x 5cm (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
Singe Use or Reusable	Single Use	Single Use
Sterilization Method	Electron beam irradiation	Electron beam irradiation
Sterilization Assurance Level (SAL)	10^{-6}	10^{-6}

Feature	MiroDry Wound Matrix (Subject Device)	Miro3D Wound Matrix (Predicate Device) K223257
Packaging	**Device package**: Packaged dry in a PETG 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 tray and snap-on lid with Tyvek lid seal **Sterile barrier:** Aluminum laminate foil pouch **Shelf box:** Cardboard
MR Compatibility	MR Safe	MR Safe
Shelf Life	25 months; may be extended with additional real-time aging	25 months; may be extended with additional real-time aging
Storage Conditions	No special storage conditions required	No special storage conditions required

VII. PERFORMANCE DATA

No performance testing was completed as prior testing of Miro3D was leveraged for MiroDry based on identical material and processing equivalence.

VIII. CONCLUSIONS

The subject MiroDry Wound Matrix has the same Intended Use as the predicate Miro3D Wound Matrix for wound management. The differences in technological characteristics do not raise different questions of safety and effectiveness as compared to Miro3D. Therefore, the subject MiroDry Wound Matrix device is substantially equivalent to the predicate Miro3D Wound Matrix device (K223257).