December 13, 2023

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

Re: K231614
Trade/Device Name: MiroTract Wound Matrix
Regulatory Class: Unclassified
Product Code: KGN
Dated: November 9, 2023
Received: November 13, 2023

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,

Julie A. Morabito -S

Julie Morabito, 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K231614

Device Name
MiroTract Wound Matrix

Indications for Use *(Describe)*
The MiroTract 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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K231614
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: Carrie Powers
Date Prepared: December 12, 2023

II. DEVICE

Trade/Proprietary Names:	MiroTract 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 (K223257).
This predicate has not been subject to a design-related recall.
No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

The Reprise Biomedical MiroTract device consists of the MiroTract Wound Matrix and disposable delivery system. The MiroTract Wound Matrix is a sterile, single use, non-crosslinked acellular wound dressing that is derived from porcine liver tissue. The porcine liver is perfusion decellularized resulting in a collagen matrix that is dried, cut to size, and radially compressed onto the guidewire of the MiroTract delivery system. The delivery system includes a guidewire and tamp tube to manually push the MiroTract Wound Matrix off the guidewire into a wound. The MiroTract Wound Matrix porous scaffold provides a protective environment for wound healing. The MiroTract Wound

Matrix is provided in two diameters (3 mm and 5 mm) and two lengths (5 cm and 9 cm). The MiroTract device is packaged dry in a plastic tray placed inside a foil pouch. The device is terminally sterilized in its packaging by e-beam irradiation. An optional Introducer Set accessory consisting of a tearaway sheath and dilator is provided in a separately packaged sterile pouch that is placed in a shelf box along with a MiroTract packaged device.

V. INDICATIONS FOR USE

The MiroTract Wound Matrix is indicated for the following:

The MiroTract 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 MiroTract Wound Matrix has the same intended use and similar technological characteristics as the predicate Miro3D Wound Matrix. Both the MiroTract and Miro3D wound matrices are made from porcine liver that is decellularized using the same perfusion process, materials, and concentrations. For Miro3D, the prepared liver tissue is dried and cut into four defined sizes in cube shape. For MiroTract, the prepared liver tissue is dried and cut into a defined size, threaded and radially compressed onto the guidewire of the MiroTract delivery system to create four MiroTract Wound Matrix sizes (3 and 5 mm Ø each offered in a 5 cm or 9 cm length). The change in wound matrix configuration (dry, uncompressed for Miro3D and dry, compressed onto a guidewire for MiroTract) does not change the principle of operation of the collagen wound matrices for wound management. Both the subject and predicate wound matrices are hydrated with the same hydrating solutions, either before or after wound placement. The MiroTract device includes a delivery system that consists of a nitinol guidewire with stainless steel tip and Pebax tamp tube. An optional Introducer Set accessory that consists of a tearaway sheath and dilator is also provided. MiroTract uses the same tray packaging material and outer foil pouch as Miro3D and is sterilized by the same sterilization method, e-beam

irradiation. The MiroTract packaging includes a packaging stopper disc to prevent the tamp tube from sliding off the guidewire when the device is removed from the tray.

Table 1: Subject vs. Predicate Wound Matrix Comparison

Feature	MiroTract Wound Matrix (Subject Device)	Miro3D Wound Matrix (Predicate Device, K223257)
Classification	Unclassified (pre-amendment)	Unclassified (pre-amendment)
Product Code	KGN	KGN
Class	Unclassified	Unclassified
Intended Use	Wound management	Wound management
Indications For Use	The MiroTract 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)	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)
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	Resorbable, animal-sourced, non-crosslinked, acellular collagen tissue matrix	Resorbable, 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

Feature	MiroTract Wound Matrix (Subject Device)	Miro3D Wound Matrix (Predicate Device, K223257)
Wound Matrix Configuration and Sizes	Compressed, cylindrical, provided in 4 sizes: Diameter (mm) x length (cm) (Model Number) • 3 x 5 (5000) • 3 x 9 (5010) • 5 x 5 (5020) • 5 x 9 (5030)	Cube shape provided in four sizes (W x L x H) (cm) (Model Number) • 2 x 2 x 2 (3000) • 3 x 3 x 2 (3005) • 5 x 5 x 2 (3010) • 10 x 5 x 2 (3015)
Wound Matrix Preparation	Use dry; may rehydrate after placement with either sterile saline or lactated Ringer's solution	Rehydrate a minimum of five minutes in either sterile saline or lactated Ringer's solution prior to application
Delivery Method	Manually placed using: • Delivery system (nitinol guidewire with stainless steel tip and Pebax tamp tube) with or without an optional Introducer Set, or • General surgical instruments	Manually placed using general surgical instruments
Packaging	• **Device package**: Packaged dry in a PETG tray with solid snap-on PETG lid and silicone foam stopper disc • **Sterile barrier:** Aluminum laminate foil pouch • **Shelf box:** Cardboard	• **Device package:** o Packaged dry in a PETG tray with notched PETG snap-on lid with Tyvek lid seal • **Sterile barrier:** Aluminum laminate foil pouch • **Shelf box:** Cardboard
Storage Conditions	No special storage conditions required	No special storage conditions required
Shelf Life	2 months (as of submission date)	25 months
Sterilization Method	Electron beam irradiation	Electron beam irradiation
Sterilization Assurance Level (SAL)	10^{-6}	10^{-6}

Feature	MiroTract Wound Matrix (Subject Device)	Miro3D Wound Matrix (Predicate Device, K223257)
MR Compatibility	**MiroTract Wound Matrix**: MR Safe **Delivery System**: MR Unsafe	MR Safe
Biocompatibility	Biocompatibility testing or justification for all applicable biological endpoints per ISO 10993-1:2018 were completed	Biocompatibility testing or justification for all applicable biological endpoints per ISO 10993-1:2018 were completed

VII. PERFORMANCE DATA

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

MiroTract Wound Matrix

1. **Biocompatibility Testing**
   a. Cytotoxicity, ISO 10993-5:2009
   b. Sensitization, ISO 10993-10:2021
   c. Intracutaneous Reactivity, ISO 10993-10:2021
   d. Acute Systemic Toxicity, ISO 10993-11: 2017
   e. Material Mediated Pyrogenicity, ISO 10993-11:2017
   f. Systemic Toxicity, ISO 10993-11:2017
   g. Implantation Testing, ISO 10993-6:2016
   h. Genotoxicity (Ames Bacterial Reverse Mutation and Mouse Lymphoma), ISO 10993-3:2014
2. **Bench Testing**
   a. Package integrity testing per ASTM F88-09, ISO 11607-1:2019, ASTM F2825-18, ASTM D4169-16, and ASTM F2096-11
   b. Package and product stability testing
   c. Collagen denaturation ASTM D3418
   d. Dimensional: MiroTract Wound Matrix is within tolerance of labeled dimensions for Length and Diameter after sterilization, environmental conditioning, and real time aging
   e. MR testing per ASTM F2052-21, ASTM F2213-17, ASTM F2182-19, ASTM F2119-07
   f. Deliverability assessment of MiroTract Wound Matrix used with the delivery system components.

VIII. CONCLUSIONS

The subject MiroTract Wound Matrix has the same Intended Use as the predicate Miro3D Wound Matrix for wound management. The differences in technological

differences have been demonstrated to not raise different questions of safety and effectiveness. Performance testing provides evidence that the MiroTract Wound Matrix performs as intended and is as safe and effective as the predicate device. Therefore, the subject MiroTract Wound Matrix device is substantially equivalent to the predicate Miro3D Wound Matrix device (K223257).