5. 510(K) SUMMARY

In accordance with 21 CFR 807.87(h) and (21 CFR 807.92) the 510(k) Summary for the Miromatrix Wound Matrix (K140510) is provided below.

Device Common Name:	Animal-derived, extracellular matrix wound care product
Device Proprietary Name:	Miromatrix Wound Matrix
Submitter:	Miromatrix Medical, Inc. 18683 Bearpath Trail Eden Prairie, MN 55347 www.miromatrix.com
Prepared By:	Stephen P. Rhodes Senior Consultant Biologics Consulting Group, Inc. Email: srhodes@bcg-usa.com
Contact:	Jeff Ross, Ph.D. VP Product Development Miromatrix Medical, Inc. 18683 Bearpath Trail Eden Prairie, MN 55347 Phone: 763-458-8801 Email: jross@miromatrix.com
Date Prepared:	February 24, 2014
Classification Regulation:	Unclassified
Panel:	General & Plastic Surgery
Product Code:	KGN
Predicate Device:	K061711, Oasis Wound Matrix Cook Biotech, Inc.

Indication for Use:

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

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

Device Description:

The Miromatrix Wound Matrix is an animal-sourced, acellular wound dressing that is derived from porcine liver tissue. The liver tissue undergoes perfusion decellularization and the resulting wound dressing is comprised primarily of collagen type I. The device is intended for use in the management of wounds. The Miromatrix Wound Matrix is terminally sterilized in its packaging and is hydrated, moist and flexible when its packaging is opened. The dressing is available in sizes ranging from 1 cm x 2 cm to 10 cm x 25 cm, and may be trimmed or cut as required.

Comparison to the Predicate:

The Miromatrix Wound Matrix has the identical indications for use as the predicate device. The technical characteristics are similar to the technological characteristics of the predicate wound dressing. Both devices are porcine-derived, acellular dressings that are comprised primarily of collagen type I. The dressings are both intended for the management of wounds.

The following GLP compliant, biocompatibility studies were conducted to evaluate the safety of the Miromatrix Wound Matrix:

Biocompatibility Testing
In Vitro Cytotoxicity
Skin Sensitization (Maximization Method)
Intracutaneous Reactivity
Acute Systemic Toxicity
In Vitro Bacterial Reverse Mutation (AMES)
In Vitro Chromosome Aberration
In Vitro Mammalian Cell Gene Mutation
Pyrogenicity
Sub-Chronic Systemic Toxicity

Per FDA guidance on shelf life, sterilization, and devices containing animal-derived material, the following laboratory studies were also conducted:

Laboratory Testing

DNA Residuals
Collagen Analysis
Viral Inactivation
Endotoxin
Expiration Dating

The biocompatibility testing showed the comparable safety profile of the Miromatrix Wound Matrix and the predicate.

Summary of Substantial Equivalence:
Based on the indications for use, technological characteristics and performance test results, the Miromatrix Wound Matrix is substantially equivalent to the predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 19, 2014

Maromatrix Medical Incorporated
% Mr. Stephen P. Rhodes
Biologics Consulting Group, Inc.
Senior Consultant
400 N. Washington Street, Suite 100
Alexandria, Virginia 22314

Re: K140510
Trade/Device Name: Miromatrix Wound Matrix
Regulatory Class: Unclassified
Product Code: KGN
Dated: March 24, 2014
Received: March 25, 2014

Dear Mr. Rhodes:

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 Industry and Consumer Education 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" (21CFR 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 Industry and Consumer Education 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,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140510

Device Name
Miromatrix Wound Matrix

Indications for Use *(Describe)*

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

Jiyoung Dang -S

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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