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

March 14, 2016

ACell, Inc
% Mr. John Smith
Hogan Lovells
555 13th St., NW
Washington, DC 20004

Re: K153754
Trade/Device Name: Micromatrix
Regulatory Class: Unclassified
Product Code: KGN
Dated: February 19, 2016
Received: February 19, 2016

Dear Mr. Smith:

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" (21 CFR 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)*
K153754

Device Name
MicroMatrix®

Indications for Use *(Describe)*
MicroMatrix® is intended for the management of topical wounds including: partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunnel/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), and draining wounds. The device is intended for one-time use.

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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510(k) SUMMARY

Date Prepared: March 10, 2016

Manufacturer Name:

Submitted by:
ACell, Inc.
6640 Eli Whitney Drive
Columbia, MD 21046

Contact Person:
Salman Elmi
Vice President, Deputy General Counsel
ACell, Inc.
Phone: (410) 953-8500
Email: salelmi@acell.com
Fax: (240) 465-8187

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name: MicroMatrix®

Common/Usual Name: Animal-derived, extracellular matrix wound care product

Regulation Name: Collagen Wound Dressing

Device Class: Unclassified

Product Code: KGN

Reviewing Panel: General & Plastic Surgery

PREDICATE DEVICE

Predicate Device: ACell Powder Wound Dressing (K060888)

DEVICE DESCRIPTION

MicroMatrix® is composed of porcine-derived extracellular matrix scaffolds, specifically known as urinary bladder matrix. The devices are supplied as a dry, absorbant, white to off-white particulate with two particle distributions, specifically <500µm and <1000µm. The particulate is packaged in an amber glass vial with butyl stopper and crimp sealed. The device is packaged in a peel-open pouch. The devices are terminally sterilized using electron beam irradiation. The device is intended for one time use. MicroMatrix® can be applied to a wound either in the dry state or pre-hydrated, and can be used in conjunction with other sheet based extracellular matrix derived scaffolds indicated for wound management.

INDICATIONS FOR USE

MicroMatrix® is intended for the management of topical wounds including: partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunnel/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), and draining wounds. The device is intended for one-time use.

PERFORMANCE DATA

Biocompatibility testing with a 10X safety factor in accordance with ISO-10993-1 (cytotoxicity, sensitization, irritation/intracutaneous reactivity, acute systemic toxicity, pyrogenicity, acute and subchronic toxicity, implantation, genotoxicity, and LAL endotoxin) was conducted to support labeling changes to describe pre-hydration of MicroMatrix®, labeling changes to describe use of MicroMatrix® with other sheet based extracellular matrix derived scaffolds indicated for wound management, and the addition of a smaller particle size specification (<500 µm). Labeling changes to describe pre-hydration of MicroMatrix® were also supported by hydration uptake testing. Labeling changes to describe use of MicroMatrix® with other sheet based extracellular matrix derived scaffolds indicated for wound management were also supported by a retrospective review of published literature describing the clinical use of urinary bladder matrix devices in wound management.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

MicroMatrix® has the same intended use as the predicate device, which is for management of wounds. The technological characteristics of the MicroMatrix® are substantially equivalent to the cleared predicate, as both are comprised of the same animal tissue-derived, collagen extracellular matrix (ECM) scaffolds that are packaged and terminally sterilized. The only minor differences between MicroMatrix® and the ACell Powder Wound Dressing predicate are the addition of a smaller particle size specification (<500 µm), and minor changes to the labeling to describe pre-hydration of MicroMatrix® and use of MicroMatrix® with other sheet based extracellular matrix derived scaffolds indicated for wound management. None of the changes alter the intended therapeutic effect of the device or its technological characteristics. The minor differences between the MicroMatrix® and the identified predicate do not raise different questions of safety or efficacy, and performance testing demonstrates that the device has comparable performance to the predicates.

CONCLUSION

Based on testing and comparison to the predicate devices, MicroMatrix® does not raise different questions of safety and effectiveness and the results support a determination of substantial equivalence through this 510(k) Premarket Notification.