October 6, 2017
ACell, Inc.
% Mr. John Smith
Hogan Lovells
555 Thirteenth Street., NW
Washington, District of Columbia 20004

Re: K172399
Trade/Device Name: MicroMatrix
Regulatory Class: Unclassified
Product Code: KGN
Dated: August 8, 2017
Received: August 8, 2017

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 (DICE) 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 (DICE) 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,

Jennifer R. Stevenson -S3

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 on last page

510(k) Number *(if known)*

K172399

Device Name

MicroMatrix®

Indications for Use *(Describe)*

MicroMatrix® is intended for the management of 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)*

X 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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K172399

510(k) SUMMARY

Date Prepared: September 27, 2017

Manufacturer Name:

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

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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

Primary Predicate Device: Cook Biotech Inc. Cook® ECM Powder (K152033)

Reference Devices: ACell Inc. MicroMatrix® (K153754)
ACell Inc. Cytal™ Wound Matrix (K152721)

DEVICE DESCRIPTION

MicroMatrix® is composed of a resorbable, porcine-derived, extracellular matrix scaffold containing epithelial basement membrane, specifically known as Urinary Bladder Matrix ("UBM"). The devices are supplied as a dry, absorbent, 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 vial is then packaged in a peel-open outer pouch that is terminally sterilized using electron beam irradiation. MicroMatrix® can be applied to a wound either in the dry state or pre-hydrated with sterile saline, and can be used in conjunction with other sheet based extracellular matrix derived scaffolds indicated for wound management. MicroMatrix is composed of resorbable

extracellular matrix particles comprised of UBM. Submitted *in vitro* and *in vivo* studies suggest that the product will be sloughed from the skin during the normal wound healing process or will be incorporated (remodeled) into the wound bed via enzymatic degradation, cellular infiltration, capillary growth, and/or integration by the surrounding host tissue. The device is intended for one time use.

INDICATIONS FOR USE

MicroMatrix® is intended for the management of 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

Packaging validation, LAL endotoxin, and shelf life studies were submitted in support of the modifications to MicroMatrix® described in this 510(k).

COMPARISON TO PREDICATE DEVICE

MicroMatrix® has the same intended use and indications for use as the predicate device. The technological characteristics of MicroMatrix® are unchanged from the previously cleared MicroMatrix® device (K153754) and substantially equivalent to the predicate in that both devices are comprised of porcine-derived, collagen extracellular matrix (ECM) scaffolds. Further, both the subject and predicate devices are particulate forms of FDA cleared extracellular matrix sheets, (Cytal® Wound Matrix and Oasis® Wound Matrix respectively) that are also intended for wound management. The subject and predicate devices are packaged and terminally sterilized. The minor differences between MicroMatrix® and the identified predicate do not raise different questions of safety or efficacy.

CONCLUSION

Based on testing and comparison to the predicate device, 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.