September 22, 2023

ACell, Inc.
Simone Oliver
Sr Specialist, Regulatory Affairs
6640 Eli Whitney Drive Suite 200
Columbia, Maryland 21046

Re: K230980
Trade/Device Name: MicroMatrix® Flex
Regulatory Class: Unclassified
Product Code: KGN
Dated: August 21, 2023
Received: August 22, 2023

Dear Simone Oliver:

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. 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 located 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.

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) for

devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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
Assistant Director
DHT4B: Division of Infection Control
and Plastic 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)*
K230890

Device Name
MicroMatrix® Flex

Indications for Use *(Describe)*
MicroMatrix® Flex 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, partial thickness burns, 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.

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510(k) SUMMARY

MicroMatrix® Flex

Submitter: ACell, Inc. (subsidiary of Integra LifeSciences Corp.)
6640 Eli Whitney Drive
Columbia, MD 21046

Contact Person: Simone Oliver
Contact Title: Senior Regulatory Affairs Specialist
Phone: +1 (301) 789-5682
Email: simone.oliver@integralife.com

Date Prepared: September 22, 2023

Trade Name: MicroMatrix® Flex

Common Name: Animal-Derived, Extracellular Matrix Wound Product

Classification Name: Collagen Wound Dressing

Regulation Number: N/A

Regulatory Class: Unclassified

FDA Product Code: KGN

Predicate Device: MicroMatrix® UBM Particulate (K172399)

Reference Devices:

- Cook Biotech Inc. – Flowable Wound Matrix (K160136)
- Integra Lifesciences Corp. – Integra Flowable Wound Matrix (K072113)

Device Description

The MicroMatrix® Flex device is a dual-syringe system for the mixing and delivery of a paste for the management of wounds. The particulate component of the device is composed of porcine-derived extracellular matrix known as urinary bladder matrix. The particulate component is identical to that particulate in the predicate device, MicroMatrix® UBM Particulate (K172399), with the standard particle size of <1000 μm. The device is packaged in a nested tray system with peel-open lids. The device is terminally sterilized using electron beam irradiation.

Intended Use/Indications for Use

MicroMatrix® Flex 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, partial thickness burns, skin tears), and draining wounds. The device is intended for one-time use.

Summary of Technological Characteristics

The technological characteristics of MicroMatrix® Flex are substantially equivalent to the cleared MicroMatrix® UBM Particulate (K172399). Both devices are single-use only, resorbable porcine animal tissue-derived collagen extracellular matrix (ECM) sheet devices.

Comparison to Predicate Device

MicroMatrix® Flex has identical intended use and indications for use as the predicate MicroMatrix® UBM Particulate device. The only minor difference is that the MicroMatrix® UBM Particulate predicate device (K172399) was cleared with the indication for second degree burns, while MicroMatrix® Flex is indicated for partial thickness burns.

The particulate manufacturing process and methods remain unchanged from the previously cleared device. The main difference between MicroMatrix® Flex and MicroMatrix® UBM Particulate is the modification to the primary packaging – the use of a syringe rather than a vial as the primary package of the particulate and how the device is dispensed by the end user. In addition, the double Sterile Barrier System (SBS) consists of nested sealed preformed rigid trays with die-cut lids rather than preformed flexible chevron pouches.

Performance Data

The subject device, MicroMatrix® Flex, and the predicate device, MicroMatrix® UBM Particulate (K172399), are comprised of identical materials and are processed and sterilized by identical methods. Biocompatibility was tested in compliance with ISO 10993-1 and the following end points were tested: cytotoxicity, sensitization, irritation/ intracutaneous reactivity, material mediated pyrogenicity, acute systemic toxicity, sub chronic toxicity, genotoxicity, intramuscular implantation (local effects after 2, 4, and 8 weeks), and biological and toxicological risk assessments were completed. Furthermore, packaging and device stability, sterilization, and usability testing were completed. Design verification (bench) testing was completed for the following performance specifications: particle size, onset temperature, tip bending, and paste preparation and dispensing. The MicroMatrix® Flex device functioned as intended and the results demonstrate that the device is substantially equivalent to the predicate device.

Conclusions

The MicroMatrix® Flex device is as safe and effective as its predicate MicroMatrix® UBM Particulate (K172399). MicroMatrix® Flex has identical intended uses and similar indications (only difference is replacement of second degree burns with partial thickness burns), similar technological characteristics, and similar principles of operation as its predicate device. The minor technological differences between MicroMatrix® Flex and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that MicroMatrix® Flex is as safe and effective as the MicroMatrix® UBM Particulate (predicate). In addition, the substantial equivalence of MicroMatrix® Flex to the predicate device, MicroMatrix® UBM Particulate, is supported by the following reference devices: Flowable Wound Matrix (K160136, Cook Biotech, Inc.) and Integra Flowable Wound Matrix (K072113, Integra LifeSciences Corp.). Both the subject device and the reference devices are packaged in a similar syringe system to allow for easy dispensability. Thus, MicroMatrix® Flex is substantially equivalent to MicroMatrix® UBM Particulate. Table 6.1 below compares the key features of the subject and predicate device.

Table 6.1 Subject Device (MicroMatrix® Flex) comparison to Predicate Device (MicroMatrix® UBM Particulate).

	Subject Device	**Predicate Device**
	ACell, Inc. MicroMatrix® Flex	*ACell, Inc.* MicroMatrix® UBM Particulate
510(k) No.	TBD	K172399
Device Class	Unclassified	Unclassified
Product Code	KGN	KGN
Classification	Dressing, Wound, Collagen	Dressing, Wound, Collagen
Material Source	Porcine Urinary Bladder Matrix (UBM)	Porcine Urinary Bladder Matrix (UBM)
Material Type	Collagen, Extracellular Matrix	Collagen, Extracellular Matrix
Crosslinked Collagen	No	No
Decellularized	Yes	Yes
Resorbable	Yes	Yes
Configuration	Particulate	Particulate
Technological Features	Device is hydrated to a paste consistency using saline in a dual syringe-to-syringe connector and then dispensed through an optional tip.	Particulate is applied directly to the wound either hydrated with saline into a paste like consistency or applied un-hydrated
Reusable	Single Use Device	Single Use Device
Biocompatible	Yes	Yes

	Subject Device	Predicate Device
Indications for Use	**MicroMatrix® Flex** 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, partial thickness burns, skin tears), draining wounds. The device is intended for one time use.	**MicroMatrix® UBM Particulate** 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.
Packaging	Preformed rigid tray with die-cut lid	Foil: PET Preformed Chevron Peel Pouch
Sterilization	E-beam	E-Beam
Storage	Store in a clean, dry environment at room temperature in an unopened and undamaged package. Protect from freezing, excessive heat, and high humidity.	Store in a clean, dry environment at room temperature in an unopened and undamaged package. Protect from freezing, excessive heat, and high humidity.