July 11, 2024

ACell, Inc
Simone Abramczyk
Senior Specialist, Regulatory Affairs
6640 Eli Whitney Dr.
Suite 200
Columbia, Maryland 21046

Re: K241724
Trade/Device Name: Cytal® Wound Matrix; Cytal® Burn Matrix
Regulatory Class: Unclassified
Product Code: KGN
Dated: June 10, 2024
Received: June 14, 2024

Dear Simone Abramczyk:

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,

Yu-chieh Chiu -S

Yu-Chieh Chiu, 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)*
K241724

Device Name
Cytal® Wound Matrix

Cytal® Burn Matrix

Indications for Use *(Describe)*
Cytal® Wound Matrix 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.

Cytal® Burn Matrix is intended for the management of wounds including: second-degree burns, 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, 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.

510(k) Summary

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92.

Submitter Information	
Name and Address	ACell, Inc. 6640 Eli Whitney Drive Ste. 200 Columbia, MD 21046
Telephone number	(301) 789-5682
Primary Contact	Simone Abramczyk
Date Summary Prepared	July 10, 2024
Name of Device	
Trade or Proprietary Name	Cytal® Wound Matrix Cytal® Burn Matrix
Device Class	Unclassified
Product Code	KGN
Predicate Information	
Predicate Device	Cytal® Wound Matrix, Cytal® Burn Matrix: K192725 & K152721

Device Description

Cytal® Wound Matrix and Cytal® Burn Matrix subject devices will be collectively referred to as "UBM devices" in this submission, unless otherwise specified.

The UBM devices are composed of a resorbable porcine–derived extracellular matrix (ECM) scaffolds, containing epithelial basement membrane, known as urinary bladder matrix (UBM). Cytal devices are supplied in single or multi-layer sheet configurations (1 to 6 layers) in sizes up to 10 cm x 15 cm (1-, 2, and 6-Layer, K152721) or 16 x 35 cm (3-Layer, K192725). Cytal sheets are provided with fenestrations in both lyophilized (1- and 2-Layer) and vacuum pressed (3- and 6-Layer) configurations. The devices are packaged in double peel-open pouches. The devices are terminally sterilized using electron beam irradiation and are intended for one-time use. UBM devices are pre-hydrated with sterile saline and applied to the wound. The devices can be cut to size and/or used in conjunction with other extracellular matrix derived scaffolds indicated for wound management, such as MicroMatrix® UBM Particulate. The devices are sloughed from the skin during the normal wound healing process or are incorporated (remodeled) into the wound bed via enzymatic degradation, cellular infiltration, capillary growth, and/or integration by the surrounding host tissue.

Indications for Use

Cytal® Wound Matrix (1-, 2-, 3-, and 6-Layer):

Cytal 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-Moh's surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, second-degree burns, skin tears), and draining wounds. The device is intended for one-time use.

Cytal® Burn Matrix:

Cytal Burn Matrix is intended for the management of wounds including: second-degree burns, partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, skin tears), and draining wounds. The device is intended for one-time use.

Technological Characteristics Compared to Predicate

The proposed UBM subject devices have the same intended use, design, materials, sterility, and fundamental operation as the predicate devices. The proposed change to extend shelf life to three (3) years does not impact the technological characteristics of the devices. The changes do not raise any new questions of safety and/or effectiveness.

Summary of Nonclinical and Clinical Testing Performed

The following performance testing has been conducted in support of the substantial equivalence determination. The testing utilized well-established methods, including those from FDA consensus standards. All testing was performed on production equivalent devices.

Performance Bench Test Results*	
Test	**Conclusion**
Dimensional Analysis / Stability	Meets Acceptance Criteria
Hydration Uptake	Meets Acceptance Criteria
Tensile Strain	Meets Acceptance Criteria
Suture Retention Strain	Meets Acceptance Criteria
Suture Retention Strength	Meets Acceptance Criteria
Delamination	Meets Acceptance Criteria
Basement Membrane Staining	Meets Acceptance Criteria
Hydrated Onset Temperature	Meets Acceptance Criteria

*Not all testing is applicable for all devices.

Sterilization/Cleaning

There are no changes in sterility as a result of the proposed changes.

Shelf Life

The shelf-life will be extended from 2 years to 3 years.

Animal Studies

No animal studies were required as appropriate verification of the subject devices was achieved based on the comparison to the predicate devices and from the results of the bench testing and engineering analysis.

Clinical Studies

No clinical studies were required as appropriate verification of the subject devices was achieved based on the comparison to the predicate devices and from the results of the bench testing and engineering analysis.

Conclusion

Based upon the intended use, design, comparison to the predicate device, and testing performed, ACell believes that the proposed modifications to the UBM subject devices do not raise any new questions of safety and effectiveness, and are therefore, substantially equivalent to the predicate Cytal Wound Matrix and Cytal Burn Matrix.