October 25, 2019

ACell, Inc.
Michelle Huettner
Director, Regulatory Affairs
6640 Eli Whitney Drive Suite 200
Columbia, Maryland 21046

Re: K192725
Trade/Device Name: Cytal Wound Matrix 3-Layer
Regulatory Class: Unclassified
Product Code: KGN
Dated: September 26, 2019
Received: September 27, 2019

Dear Michelle Huettner:

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,

For Cynthia J. Chang, Ph.D.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192725

Device Name
Cytal® Wound Matrix 3-Layer

Indications for Use *(Describe)*
Cytal® Wound Matrix 3-Layer 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)*

☒ 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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K192725 510(k) SUMMARY
Cytal® Wound Matrix 3-Layer

Submitter:	ACell, Inc. 6640 Eli Whitney Drive Columbia, MD 21046
Contact Person:	Michelle Huettner
Contact Title:	Director of Regulatory Affairs ACell, Inc.
Phone:	(765) 464-8198 ext 135
Facsimile:	410-715-4511
Date Prepared:	October 25, 2019
Trade Name:	Cytal® Wound Matrix 3-Layer
Common Name:	Animal-Derived, Extracellular Matrix Wound Care Product
Classification Name:	Dressing, Wound, Collagen
Regulation Number:	N/A
Regulatory Class:	Unclassified
FDA Product Code:	KGN
Predicate Device:	ACell, Inc. Cytal® Wound Matrix (K152721)
Reference Devices:	ACell, Inc. Gentrix Surgical Matrix Thick; Gentrix® Surgical Matrix Extend (K170763)

Device Description

Cytal® Wound Matrix 3-Layer is composed of a resorbable, porcine–derived, extracellular matrix (ECM) scaffold containing epithelial basement membrane, specifically known as urinary bladder matrix (UBM). The devices are supplied in fenestrated sheet configurations up to 16 cm x 35 cm and packaged in double peel-open pouches. The devices are terminally sterilized using electron beam irradiation. Cytal Wound Matrix 3-Layer is pre-hydrated with sterile saline and applied to the wound. The device can be cut to different sizes. The device is intended for one time use.

Intended Use/Indications for Use

Cytal® Wound Matrix 3-Layer 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.

Summary of Technological Characteristics

The technological characteristics of the modified Cytal Wound Matrix 3-Layer (subject device) are substantially equivalent to the cleared Cytal Wound Matrix predicate. The subject and predicate devices have substantially equivalent raw materials, manufacturing processes, and sterilization requirements. More specifically, the devices are fenestrated wound dressings composed of 3-layers of a resorbable, porcine-derived, extracellular matrix scaffold containing epithelial basement membrane, known as urinary bladder matrix (UBM). The devices are manufactured using the same processes, except for utilizing the same layering configuration method cleared in ACell's reference Gentrix Surgical Matrix Thick device (K170763) to achieve the larger device size. The single use only subject and predicate devices are vacuum-pressed to dehydrate the device and terminally sterilized using electron beam irradiation to achieve a sterilization assurance level of 10^{-6}. Updated packaging has been implemented to account for the device size. The minor differences cited above for the Cytal Wound Matrix 3-Layer and the identified predicate do not raise different questions of safety or effectiveness, and performance testing demonstrates that the device has comparable performance to the predicate.

A table comparing the key features of the subject and predicate devices is provided below.

ACell, Inc.	**Subject Device**	**Predicate Device**	**Reference Device**
	Cytal® Wound Matrix 3-Layer	**Cytal® Wound Matrix**	**Gentrix® Surgical Matrix Thick; Gentrix® Surgical Matrix Extend**
510(k) No.	K192725	K152721	K170763
Device Class	Unclassified	Unclassified	Class II
Product Code	KGN	KGN	FTM, OXH, OXK
Classification	Dressing, Wound, Collagen	Dressing, Wound, Collagen	Surgical Mesh
Indications for Use/ Intended Use	Cytal Wound Matrix 3-Layer 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 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.	Gentrix Surgical Matrix Thick and Gentrix Surgical Matrix Extend are intended for implantation to reinforce soft tissue where weakness exists in patients requiring gastroenterological or plastic & reconstructive surgery. Reinforcement of soft tissue within gastroenterological and plastic & reconstructive surgery includes, but is not limited to, the following procedures: hernia and body wall repair, colon and rectal prolapse repair, tissue repair, and esophageal repair.

ACell, Inc.	Subject Device	Predicate Device	Reference Device
	Cytal® Wound Matrix 3-Layer	**Cytal® Wound Matrix**	**Gentrix® Surgical Matrix Thick; Gentrix® Surgical Matrix Extend**
Material Source	Porcine Urinary Bladder Matrix (UBM)	Porcine Urinary Bladder Matrix (UBM)	Porcine Urinary Bladder Matrix (UBM)
Material Type	Collagen, Extracellular Matrix	Collagen, Extracellular Matrix	Collagen, Extracellular Matrix
Resorbable	Yes	Yes	Yes
Number of Layers	3-Layers	2-,3-,6-,8-Layers	8- Layers
Clinically Relevant Sizes (Nominal)	16 cm x 25 cm & 16 cm x 35 cm	3 cm x 3.5 cm to 10 cm x 15 cm	Up to 30 cm x 40 cm
For Single Use	Yes	Yes	Yes
Sterilization	Electron-beam Irradiation	Electron-beam Irradiation	Electron-beam Irradiation
Packaging	Dual Foil:PET Sterile Barrier System	Dual Tyvek:PET Sterile Barrier System	Dual Foil:PET Sterile Barrier System
Storage & Handling Conditions on Labeling	Store in a clean, dry environment at room temperature	15 - 35°C	Store in a clean, dry environment at room temperature

Performance Data

The following bench testing was performed to ensure that the additional Cytal Wound Matrix 3-Layer device sizes met the clinically relevant user needs, design inputs, and specifications to demonstrate substantial equivalence to the predicate device:

- Suture retention strain
- Tensile strain
- Hydration uptake
- Dimensional analysis
- Packaging performance

In addition, design validation testing was completed via clinician feedback and simulated use testing. In all instances, Cytal Wound Matrix 3-Layer functioned as intended and the results of the testing were as expected. The results of the design verification bench testing and design validation testing demonstrate that the device is substantially equivalent to the predicate device. There were no pre-clinical animal studies or clinical studies conducted to support the substantial equivalence of the subject device to the predicate device.

Conclusions

The subject larger size (16 cm x 25 cm & 16 cm x 35 cm) Cytal Wound Matrix 3-Layer is as safe and effective as the Cytal Wound Matrix 2-, 3-, 6-, 8-Layers currently offered in sizes 3 cm x 3.5 cm to 10 cm x 15 cm. Cytal Wound Matrix 3-Layer has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. In addition, the minor technological differences between the larger Cytal Wound Matrix 3-Layer and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrates that the larger Cytal Wound Matrix 3-Layer is as safe and effective as the cleared Cytal Wound Matrix. Thus, the modified Cytal Wound Matrix is substantially equivalent to the cleared Cytal Wound Matrix (K152721).