



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center – WO66-G609  
Silver Spring, MD 20993-0002

December 8, 2015

ACell Incorporated  
Thomas Gilbert, Ph.D.  
Chief Science Officer  
6640 Eli Whitney Drive  
Columbia, Maryland 21046

Re: K152721  
Trade/Device Name: Cytal™ Wound Matrix  
Regulatory Class: Unclassified  
Product Code: KGN  
Dated: December 1, 2015  
Received: December 1, 2015

Dear Dr. Gilbert:

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" (21CFR 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

## Indications for Use

510(k) Number (if known)

K152721

Device Name

Cytal® Wound 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.

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)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

### FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services  
Food and Drug Administration  
Office of Chief Information Officer  
Paperwork Reduction Act (PRA) Staff  
[PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov)

*“An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.”*

**510(K) SUMMARY**

**Date Prepared:** September 21, 2015

**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](mailto:salelmi@acell.com)  
Fax: (240) 465-8187

**DEVICE NAME AND CLASSIFICATION**

*Trade/Proprietary Name:* Cytal™ Wound Matrix

*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:* MatriStem® Wound Matrix (K112409)

**DEVICE DESCRIPTION**

Cytal™ Wound Matrix is composed of porcine-derived extracellular matrix scaffolds, specifically known as urinary bladder matrix. The devices are supplied in single and multi-layer sheet configurations (1 to 8 layers) in sizes up to 10 cm x 15 cm, and can be provided with or without fenestrations in both lyophilized and vacuum pressed configurations. The device is packaged in double peel-open pouches. The devices are terminally sterilized using electron beam irradiation. The device is intended for one time use.

The technical specifications for the Cytal™ Wound Matrix are as follows, depending upon whether the device is fenestrated or unfenestrated:

- If fenestrated: Device will be provided dry in sheet sizes up to 10 x 15 cm in double sterile barrier packaging. Device will be fenestrated appropriately according to size with parallel slits along the long axis.
- If unfenestrated: Device will be provided dry in sheet sizes up to 10 x 15 cm in double sterile barrier packaging.

**INDICATIONS FOR 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.

**COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE**

Cytal™ Wound Matrix has the same intended use as predicate device, which is for management of wounds. The technological characteristics of the Cytal™ Wound Matrix are substantially similar to the cleared predicate, as both are comprised of animal tissue-derived, collagen extracellular matrix (ECM) scaffolds supplied in a rectangular sheet configuration that are packaged and terminally sterilized. The available sizes of the subject device (25 – 150 cm<sup>2</sup>) are consistent with the range of sizes of the predicate device (16 – 280 cm<sup>2</sup>). The subject device and the predicate device both consist of multilaminar sheets ranging from 1-8 layers. The minor difference between the Cytal™ Wound Matrix and the identified predicate with regard to dehydration method (lyophilized vs. vacuum pressed) does not raise different questions of safety or efficacy and performance testing demonstrates that the device has comparable performance to the predicate.

**PERFORMANCE DATA****Biocompatibility Testing**

The same material used in the Cytal™ Wound Matrix underwent the following biocompatibility testing on sterilized devices per ISO-10993-1 standard: cytotoxicity, sensitization, irritation/intracutaneous reactivity, acute systemic toxicity, pyrogenicity, subacute and subchronic toxicity and implantation, genotoxicity, and LAL endotoxin. The results of these tests provided evidence that the Cytal™ Wound Matrix meets biocompatibility requirements of the ISO standard.

**Mechanical Testing**

The same material used in the Cytal™ Wound Matrix was tested for suture retention strength. The results of the mechanical testing provided evidence that the Cytal™ Wound Matrix provides adequate mechanical strength for its application.

**CONCLUSION**

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