May 11, 2018

ACell, Inc.
c/o John Smith
Hogan Lovells
555 Thirteenth St., NW
Washington, District of Columbia 20004

Re: K180776
Trade/Device Name: Cytal Wound Particulate
Regulatory Class: Unclassified
Product Code: KGN
Dated: April 13, 2018
Received: April 13, 2018

Dear John 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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

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)*
K180776

Device Name
Cytal® Wound Particulate

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

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.

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

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510(k) SUMMARY
ACell Inc.'s Cytal® Wound Particulate

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

Contact Person: Andrea Pilon Artman
Phone: 410-953-8549
Facsimile: 410-715-4511

Date Prepared: May 10, 2018

Trade Name: Cytal® Wound Particulate
Common Name: Animal-Derived, Extracellular Matrix Wound Care Product
Classification Name: Dressing, Wound, Collagen
Regulatory Class: Unclassified
Product Code: KGN

Predicate Device: ACell Inc. Cytal® Wound Matrix (K152721)

Reference Devices: ACell Inc. MicroMatrix® (K172399)
Cook Biotech Inc. Cook® ECM Powder (K152033)

Device Description

Cytal® Wound Particulate 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 sized <1000µm in multi-layer configurations (2 to 8 layers). 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. Cytal® Wound Particulate 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. *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.

Intended Use/Indications for Use

Cytal® Wound 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.

Summary of Technological Characteristics

The technological characteristics of the Cytal® Wound Particulate are substantially equivalent to the cleared Cytal® predicate, as both are comprised of the same animal tissue-derived, collagen extracellular matrix (ECM) scaffold material. The devices are manufactured using the same processes except for the addition of a manufacturing process to reduce the size of the wound dressing from a layered sheet configuration to a particulate. Both the subject and predicate devices are terminally sterilized. Updated packaging has been implemented to account for the reduction in device size.

The minor differences between the Cytal® Wound Particulate and the identified predicate do not raise different questions of safety or efficacy, and performance testing demonstrates that the device has comparable performance to the predicate.

Performance Data

The following testing was performed to address the size change and to demonstrate substantial equivalence to the predicate device:

- Particle Size Characterization
- Dispensing (Deployability)
- Sterilization Validation
- Endotoxin

In all instances, the Cytal® Wound Particulate functioned as intended and the results observed were as expected.

Conclusions

The Cytal® Wound Particulate is as safe and effective as the Cytal® Wound Matrix. The Cytal® Wound Particulate has the same intended uses, indications, and principles of operation as its predicate device. The minor technological differences between the Cytal® Wound Particulate and its predicate device do not raise different questions of safety or effectiveness. Performance data demonstrate that the Cytal® Wound Particulate is as safe and effective as the predicate device.