November 22, 2019

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

Re: K191734
Trade/Device Name: MatriStem UBM Pericardial Patch
Regulation Number: 21 CFR 870.3470
Regulation Name: Intracardiac Patch Or Pledget Made Of Polypropylene, Polyethylene Terephthalate, Or Polytetrafluoroethylene
Regulatory Class: Class II
Product Code: PSQ
Dated: October 30, 2019
Received: October 31, 2019

Dear Ms. 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,

Rachel Neubrander
Assistant Director
DHT2B: Division of Circulatory Support,
Structural and Vascular Devices
OHT2: Office of Cardiovascular 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)*

K191734

Device Name
MatriStem UBM™ Pericardial Patch

Indications for Use *(Describe)*
The MatriStem UBM™ Pericardial Patch is intended for the reconstruction and repair of the pericardium.

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.

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
PRAStaff@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
MatriStem UBM™ Pericardial Patch

Submitter: ACell, Inc.
6640 Eli Whitney Drive, Suite 200
Columbia, MD 21046

Contact Person: Michelle Huettner
Contact Title: Director of Regulatory Affairs
Phone: 765-464-8198 ext 135
Facsimile: 410-715-4511

Date Prepared: November 21, 2019

Trade Name: MatriStem UBM™ Pericardial Patch

Common Name: Animal-Derived, Extracellular Matrix Pericardial Patch Product

Classification Name: Patch, Pledget and Intracardiac

Regulation Number: 21 C.F.R. §870.3470

Regulatory Class: Class II

FDA Product Code: PSQ

Predicate Device: CorMatrix Pericardial Patch/ CorMatrix ECM for Pericardial Closure (K051405)

Reference Devices: ACell Gentrix Surgical Matrix (2, 3, 6, 8 layer) (K162554), ACell Gentrix Surgical Matrix Thick (8 layer) (K170763), Edwards Bovine Pericardial Patch (K082139)

Device Description

The MatriStem UBM Pericardial Patch is a 4-layer multi-laminate device comprised of stacked urinary bladder matrix (UBM) sheets. The Pericardial Patch serves as a patch to reconstruct the pericardium and restore the native anatomy. The Pericardial Patch is available in three sizes: 7x10 cm, 7x15 cm, and 10x15 cm. Each device is packaged in a double peel-open pouch and an outer carton. The device is terminally sterilized using electron-beam irradiation.

Intended Use/Indications for Use

The MatriStem UBM Pericardial Patch is intended for the reconstruction and repair of the pericardium.

Summary of Technological Characteristics

The technological characteristics of the ACell MatriStem UBM Pericardial Patch are substantially equivalent to the cleared CorMatrix Pericardial Patch (K051405). Both are single-use only, resorbable porcine animal tissue-derived collagen extracellular matrix (ECM) sheet devices in rectangular configurations. The CorMatrix Pericardial Patch (K051405) is manufactured from porcine sub intestinal submucosa (SIS) and the subject device is manufactured from porcine urinary bladder matrix (UBM). The porcine small intestine tissue and porcine bladder tissue have similar mechanical properties and similar composition. The ACell MatriStem UBM Pericardial Patch is technologically very similar to ACell's cleared MatriStem UBM devices such as the Gentrix Surgical Matrix and Gentrix Surgical Matrix Thick (K162554, K170763) which are also multi-laminate sheets manufactured from the same porcine urinary bladder matrix material, packaged in the same sterile barrier system with dual Foil:PET pouches, and also undergo terminal sterilization with electron beam irradiation.

A table comparing the key features of the subject and predicate devices is provided in Table 1: Comparison of Subject Device and Predicate Devices.

Table 1: Comparison Table of Subject Device and Predicate Devices

	ACell, Inc. *Subject Device* MatriStem UBM™ Pericardial Patch	**CorMatrix Cardiovascular, Inc.** *Primary Predicate Device* CorMatrix Pericardial Patch (CorMatrix ECM for Pericardial Closure)	**ACell, Inc.** *Reference Device* Gentrix® Surgical Matrix (2-Layer, 3-Layer, 6-Layer, 8-Layer), Gentrix® Surgical Matrix Thick	**Edwards Lifesciences** *Reference Device* Bovine Pericardial Patch
510(k) No.	K191734	K051405	K162554, K170763	K082139
Device Class	Class II	Class II	Class II	Class II
Product Code	PSQ	DXZ	FTM, OXH	DXZ
Classification	Patch, Pledget and Intracardiac	Patch, Pledget and Intracardiac	Surgical Mesh	Patch, Pledget and Intracardiac
Intended Use / Indications for Use	The MatriStem UBM™ Pericardial Patch is intended for the reconstruction and repair of the pericardium.	The CorMatrix Pericardial Patch is intended for the reconstruction and repair of the pericardium.	<u>K162554 Indications for Use:</u> Gentrix® Surgical Matrix 2-layer and 3-layer is intended for implantation to reinforce soft tissue where weakness exists in patients requiring urological, gastroenterological, or plastic & reconstructive surgery. Reinforcement of soft tissue within urological, 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. Gentrix® Surgical Matrix 6-layer and 8-layer 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. <u>K170763 Indications for Use:</u> 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	The pericardial patch is intended for use as a surgical patch material for: augmenting the patient's own pericardium to assist in closure following open-heart surgery, intracardiac defects, septal defects and annulus repairs, cardiac and vascular reconstruction and repairs, peripheral vascular reconstruction and repairs, great vessel reconstruction and repairs, and suture-line buttressing.

	ACell, Inc. *Subject Device* MatriStem UBM™ Pericardial Patch	**CorMatrix Cardiovascular, Inc.** *Primary Predicate Device* CorMatrix Pericardial Patch (CorMatrix ECM for Pericardial Closure)	**ACell, Inc.** *Reference Device* Gentrix® Surgical Matrix (2-Layer, 3-Layer, 6-Layer, 8-Layer), Gentrix® Surgical Matrix Thick	**Edwards Lifesciences** *Reference Device* Bovine Pericardial Patch
			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.	
Material Source	Porcine Urinary Bladder Matrix (UBM)	Porcine Sub Intestinal Submucosa (SIS)	Porcine Urinary Bladder Matrix (UBM)	Bovine Pericardium
Material Type	Collagen, Extracellular Matrix	Collagen, Extracellular Matrix	Collagen, Extracellular Matrix	Bovine Tissue
Crosslinked Collagen	No	No	No	Yes
Resorbable	Yes	Yes	Yes	Yes
Configuration	Rectangular Sheets	Rectangular Sheets	Rectangular Sheets	Rectangular Sheets
# of Layers	4	4	Gentrix Surgical Matrix: 2, 3, 6, 8 Gentrix Surgical Matrix Thick: 8	Tissue Thickness 0.5 mm +/- 0.25 mm
Nominal Sizes (cm)	7 x 10 cm 7 x 15 cm 10 x 15 cm	7 x 10 cm 7 x 15 cm	Gentrix Surgical Matrix: Up to 10 x 15 cm Gentrix Surgical Matrix Thick: Up to 30 x 40 cm	10 x 15 cm
Reusable or Single Use	Single Use Device	Single Use Device	Single Use Device	Single Use Device
Packaging	Dual Foil:PET Pouch System	Dual Pouch System	Dual Foil:PET Pouch System	Packaged sterile in container with glutaraldehyde
Sterilization	Electron beam irradiation	Ethylene oxide	Electron beam irradiation	XenoLogiX process, terminally sterilized in glutaraldehyde

Performance Data and Animal Testing

The following bench testing was performed to ensure the MatriStem UBM Pericardial Patch met its clinically relevant design input requirements and specifications: basement membrane presence, hydration uptake, moisture content, hydrated onset temperature, endotoxin, bioburden enumeration, suture retention strength, tensile strength, dimensional confirmation, device stiffness, tearing strength, and ball burst strength. Existing test data was leveraged from the cleared Gentrix Surgical Matrix reference devices (K162554, K170763) for the following tests because they were not impacted for the MatriStem UBM Pericardial Patch made of the same porcine urinary bladder matrix material: sterilization validation, biocompatibility, shelf-life, viral inactivation, and packaging testing. Confirmatory cytoxicity testing was also performed on production-equivalent MatriStem UBM Pericardial Patch (subject device).

In addition, the performance of the MatriStem UBM Pericardial Patch was shown to be substantially equivalent to the predicate CorMatrix Pericardial Patch (also referred to as the CorMatrix ECM for Pericardial Closure) through design validation testing. This was demonstrated via a 90-day Good Laboratory Practices (GLP) animal study on 12 total pigs. A pericardial defect was created on each pig. Two (2) pigs did not have the pericardial defect repaired (sham), five (5) pigs had the defect repaired with the ACell MatriStem UBM Pericardial Patch, and five (5) pigs had the defect repaired with the predicate CorMatrix Pericardial Patch. All acceptance criteria were met for this animal study including: demonstration of device biocompatibility through a full necropsy examination and histology evaluation of the local tissues post device implantation and observation for 90 days, demonstration of similar or improved cardiac function through echocardiography measurements compared to the sham, and demonstration of similar or improved cellular infiltration and remodeling histopathologic outcomes versus the predicate CorMatrix device. The animal study successfully evaluated the safety and biological response of the MatriStem UBM Pericardial Patch in a porcine model of pericardial repair.

The MatriStem UBM Pericardial Patch functioned as intended during all tests. The results of the bench testing and animal testing demonstrate that the device is substantially equivalent to the predicate device. There were no clinical studies conducted to support the substantial equivalence of the subject device to the predicate device.

Conclusions

The MatriStem UBM Pericardial Patch is as safe and effective as the CorMatrix Pericardial Patch/ CorMatrix ECM for Pericardial Closure (K051405). The MatriStem UBM Pericardial Patch has the same intended use and indications for use, and similar technological characteristics and principles of operation as its predicate device. The minor technological differences between the MatriStem UBM Pericardial Patch and its predicate devices raise no new issues of safety or effectiveness.
Performance data and animal testing demonstrates that the MatriStem UBM Pericardial Patch is as safe and effective as the CorMatrix Pericardial Patch. Thus, the MatriStem UBM Pericardial Patch is substantially equivalent.