October 25, 2017

ACell, Incorporated
% John Smith, M.D., J.D.
Hogan Lovells US LLP
555 Thirteenth Street, NW
Washington DC, District of Columbia 20004

Re: K170763
Trade/Device Name: Gentrix™ Surgical Matrix Thick; Gentrix™ Surgical Matrix Extend
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: FTM, OXH, OXK
Dated: March 13, 2017
Received: March 13, 2017

Dear Dr. Smith:

This letter corrects our substantially equivalent letter of June 8, 2017. 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 (DICE) 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" (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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) 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,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170763

Device Name
Gentrix Surgical Matrix Thick and Gentrix Surgical Matrix Extend

Indications for Use *(Describe)*
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.

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 Gentrix™ Surgical Matrix Thick and Gentrix™ Surgical Matrix Extend

Date Prepared: March 13, 2017

Manufacturer Information

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

Contact Person: Salman Elmi
VP and Deputy General Counsel; Head of Regulatory Affairs
ACell, Inc.
Phone: (410) 953-8500
Facsimile: (240) 465-8187

Device Name and Classification

Trade/Proprietary Name:	Gentrix™ Surgical Matrix Thick and Gentrix™ Surgical Matrix Extend
Common or Usual Name:	Surgical Mesh, ECM, Surgical Scaffold
Regulation Name:	21 CFR 878.3300; Surgical Mesh
Regulatory Class:	Class II
Product Code:	FTM, OXH, OXK
Predicate Devices:	ACell, Inc. Gentrix™ Surgical Matrix 8 Layer (K162554)

Device Description

The Gentrix™ Surgical Matrix Thick and Gentrix™ Surgical Matrix Extend devices are composed of porcine-derived extracellular matrix scaffolds, specifically known as urinary bladder matrix. The devices are supplied in an eight-layer sheet configuration in sizes up to 30 cm x 40 cm, and packaged in double peel-open pouches. The devices are terminally sterilized using electron beam irradiation. The implantable biomaterial is a resorbable extracellular matrix scaffold that will incorporate (remodel) into the body through cellular infiltration, capillary growth, and integration by the surrounding host tissue. Animal studies have shown device resorption in approximately 240 days.

Intended Use / Indications for 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.

Summary of Technological Characteristics

Gentrix™ Surgical Matrix Thick and Gentrix™ Surgical Matrix Extend configurations have identical indications for use, intended use, materials, manufacturing processes, packaging materials, and sterilization requirements as the predicate device, and are identical or similar in performance characteristics when compared to the predicate Gentrix™ Surgical Matrix 8-Layer (K162554) device. The Performance evaluations described below were completed to demonstrate equivalence to the predicate device.

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

	ACell, Inc. Gentrix™ Surgical Matrix Thick and Gentrix™ Surgical Matrix Extend	**ACell, Inc.** Gentrix™ Surgical Matrix 8-Layer
510(k) No.	TBD	K162554
Device Class	Class II	Class II
Product Code	FTM, OXH	FTM, OXH
Classification	ECM, Surgical Mesh	ECM, Surgical Mesh
Intended Use / Indications for Use	The 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.	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.
Material Source	Porcine Urinary Bladder	Porcine Urinary Bladder
Material Type	Collagen, Extracellular Matrix	Collagen, Extracellular Matrix
Resorbable	Yes	Yes
Configuration	Sheets	Sheets
Nominal Sizes (cm)	Up to 30 x 40	Up to 10 x 15
Reusable	Single Use Device	Single Use Device
Packaging	Dual Foil:PET Pouch System	Dual Foil:PET Pouch System
Sterilization	electron beam irradiation	electron beam irradiation

Performance Data

Bench – Biocompatibility Testing

The subject devices were evaluated for biocompatibility per ISO-10993 including the following: cytotoxicity, sensitization, irritation/intracutaneous reactivity, acute systemic toxicity, pyrogenicity, subacute and subchronic toxicity and implantation, genotoxicity, hemocompatibility, and LAL endotoxin. The evaluation demonstrates that the subject devices meet the biocompatibility requirements of the ISO standard.

Bench – Mechanical Testing
Gentrix™ Surgical Matrix Thick and Gentrix™ Surgical Matrix Extend configurations were tested for the following: tensile strength, suture retention strength, ball burst strength, and tear strength. The results of the mechanical testing provided evidence that the subject devices are substantially equivalent to the predicate device, and provide adequate mechanical strength for its application throughout its labeled shelf life.

Bench – Material Characterization
Gentrix™ Surgical Matrix Thick and Gentrix™ Surgical Matrix Extend configurations were tested for the following: stiffness, moisture content, hydration uptake, and hydrated onset temperature. The results of the material characterization testing provided evidence that the subject devices are substantially equivalent to the predicate device and provide adequate performance for its application throughout its labeled shelf life.

Animal Testing
Gentrix™ Surgical Matrix Thick and Gentrix™ Surgical Matrix Extend configurations were evaluated in a pre-clinical porcine model of incisional ventral hernia repair through full device degradation and remodeling. These animal studies provide evidence of full host tissue integration and demonstrate substantially equivalent performance between the subject and predicate devices. In addition, these results support the biocompatibility of the subject devices.

Clinical
No Clinical data was provided in support of this clearance.

Conclusions

The Gentrix™ Surgical Matrix Thick and Gentrix™ Surgical Matrix Extend are as safe and effective as the Gentrix™ Surgical Matrix 8-Layer. The Gentrix™ Surgical Matrix Thick and Gentrix™ Surgical Matrix Extend have identical intended uses, indications, and principles of operation; additionally the subject and predicate devices have identical or similar technological characteristics. The minor technological differences between the Gentrix™ Surgical Matrix Thick and Gentrix™ Surgical Matrix Extend and the predicate device raise no new issues of safety or effectiveness. Performance data demonstrate that the Gentrix™ Surgical Matrix Thick and Gentrix™ Surgical Matrix Extend are as safe and effective as the Gentrix™ Surgical Matrix 8-Layer. Thus, the Gentrix™ Surgical Matrix Thick and Gentrix™ Surgical Matrix Extend are substantially equivalent to the predicate device.