DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

October 21, 2016

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

Re: K162554
Trade/Device Name: Gentrix™ Surgical Matrix 2-Layer, 3-Layer, 6-Layer, 8 Layer
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: FTM, OXH
Dated: October 19, 2016
Received: October 19, 2016

Dear Dr. 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.

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" (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 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)*
K162554

Device Name
Gentrix™ Surgical Matrix 2-Layer, 3-Layer, 6-Layer, 8-Layer

Indications for Use *(Describe)*
Gentrix™ Surgical Matrix 2-layer and 3-layer are 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.

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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510(k) Summary

This summary of 510(k) safety and effectiveness is being submitterd in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.

Date Prepared: October 19, 2016

Manufacturer Name:

Submitted by: ACell, Inc.
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DEVICE NAME AND CLASSIFICATION

510(k) Number:	K162554
Trade/Proprietary Name:	Gentrix™ Surgical Matrix 2-Layer, 3-Layer, 6-Layer, 8-Layer
Common/Usual Name:	Surgical Mesh, ECM, Surgical Scaffold
Regulation Name:	Surgical Mesh
Device Class:	Class II, 21 CFR 878.3300
Product Code:	FTM, OXH
Reviewing Panel:	General & Plastic Surgery
Predicate Devices:	MatriStem® Surgical Matrix RS, PSM, PSMX (K141084)
Reference Devices:	ACell Surgical Mesh ML, MLPlus (K041140)

DEVICE DESCRIPTION

Gentrix™ Surgical Matrix 2-Layer, 3-Layer, 6-Layer, 8-Layer devices are composed of porcine-derived extracellular matrix scaffolds, specifically known as urinary bladder matrix. The devices are supplied in multi-layer sheet configurations in sizes up to 10 cm x 15 cm, and packaged in double peel-open foil pouches. The devices are terminally sterilized using electron beam irradiation.

INDICATIONS FOR USE

Gentrix™ Surgical Matrix 2-layer and 3-layer are 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.

EQUIVALENCE TO MARKETED DEVICES

Gentrix™ Surgical Matrix 2-Layer, 3-Layer, 6-Layer, 8-Layer have the same intended use as the predicate and reference surgical meshes, which is to reinforce soft tissue where weakness exists. The technological characteristics of the Gentrix™ Surgical Matrix 2-Layer, 3-Layer, 6-Layer, and 8-Layer are substantially similar to the cleared predicate and reference devices, as all are identical in materials and manufacturing to the predicate and reference devices. Gentrix™ Surgical Matrix, the predicate device, and the reference device are comprised of animal tissue-derived, collagen extracellular matrix (ECM) scaffolds supplied in a multilaminate rectangular sheet configuration that are packaged and terminally sterilized. The available sizes of the subject device (8 – 150 cm^2) are identical with the range of sizes of the predicate device, and within the range of the cleared reference device (8 – 280 cm^2). The packaging system for Gentrix™ Surgical Matrix 2-Layer, 3-Layer, 6-Layer, 8-Layer was validated per ANSI/AAMI/ISO 11607-1 and -2, and is substantially similar to the packaging system used for the cleared predicate and reference devices. The minor differences between the Gentrix™ Surgical Matrix 2-Layer, 3-Layer, 6-Layer, 8-Layer and the predicate and reference devices do not raise different questions of safety or efficacy and performance testing demonstrates that the device has comparable performance to the predicates.

PERFORMANCE DATA

Biocompatibility Testing

Gentrix™ Surgical Matrix 2-Layer, 3-Layer, 6-Layer, 8-Layer underwent the following biocompatibility testing on sterilized devices per FDA's extent of recognition of ISO-10993-1 standard for a permanently implanted device: cytotoxicity, sensitization, irritation/intracutaneous reactivity, acute systemic toxicity, pyrogenicity, subacute and subchronic toxicity and implantation, genotoxicity, hemocompatibility, and LAL endotoxin. The results of these tests provided evidence that the Gentrix™ Surgical Matrix is substantially equivalent to the predicate and reference devices and meets biocompatibility requirements of the ISO standard.

Mechanical Testing

Gentrix™ Surgical Matrix 2-Layer, 3-Layer, 6-Layer, 8-Layer material was tested for the following: tensile strength, suture retention strength, ball burst strength, delamination strength, tear strength, and stiffness test. The results of the mechanical testing provided evidence that the Gentrix™ Surgical Matrix is substantially equivalent to the predicate and reference devices and provides adequate mechanical strength for its application throughout its labeled shelf life.

Material Characterization

Gentrix™ Surgical Matrix 2-Layer, 3-Layer, 6-Layer, 8-Layer material was tested for the following: moisture content, hydration uptake, and hydrated onset temperature. The results of the material characterization testing provided evidence that the Gentrix™ Surgical Matrix is substantially equivalent to the predicate and reference devices and provides adequate performance for its application throughout its labeled shelf life

CONCLUSION

Based on direct testing and comparison to predicate and reference devices, Gentrix™ Surgical Matrix 2-Layer, 3-Layer, 6-Layer, 8-Layer do not raise different questions of safety and effectiveness and the results support a determination of substantial equivalence through this 510(k) Premarket Notification.