DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

February 24, 2017

Lifecell Corporation
Ms. Anuja Yardi
Regulatory Affairs Specialist
One Millennium Way
Branchburg, New Jersey 08876

Re: K162752
Trade/Device Name: ARTIA Reconstructive Tissue Matrix Perforated
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: FTM, OXH
Dated: January 25, 2017
Received: January 26, 2017

Dear Ms. Yardi:

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)*
K162752

Device Name
ARTIA Reconstructive Tissue Matrix-Perforated

Indications for Use *(Describe)*
ARTIA Tissue Matrix is intended for use as a soft tissue patch to reinforce soft tissue where weakness exists and for the surgical repair of damaged or ruptured soft tissue membranes which require the use of reinforcing or bridging material to obtain the desired surgical outcome. The implant is intended for reinforcement in plastic and reconstructive surgery.

ARTIA Tissue Matrix is intended for single patient, one time use only.

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."

7. 510(k) Summary

7.1 SUBMITTER

Name and Address of Submitter:
LifeCell Corporation
One Millennium Way
Branchburg, NJ 08876 USA

Contacts:
Anuja Yardi
Regulatory Affairs Specialist
Phone: (908) 947-1018
Fax: (908) 947-1095

Mira Leiwant
Senior Director, Quality Engineering and Regulatory Affairs
Phone: (908) 809-7747
Fax: (908) 947-1095

Prepared by and Date:
Anuja Yardi
September 29, 2016

7.2 DEVICE

Name of Device: ARTIA™ Reconstructive Tissue Matrix Perforated
Common or Usual Name: Surgical Mesh
Classification Name: Surgical Mesh- (21 C.F.R. §878.3300)
Device Class: Class II
Product Code: FTM and OXH

7.3 PREDICATE DEVICE

Predicate Device:
ARTIA Reconstructive Tissue Matrix (cleared as HPTM via K142326)
The predicate has not been subject to a design-related recall.

Reference Device:
Strattice Tissue Matrix Perforated (K150712) – LifeCell Corporation
The reference device has not been subject to a design-related recall.

7.4 DEVICE DESCRIPTION

ARTIA Reconstructive Tissue Matrix Perforated (ARTIA Tissue Matrix Perforated) is a surgical mesh that is derived from porcine dermis and is processed and preserved in a patented phosphate buffered aqueous solution containing matrix stabilizers. ARTIA Tissue Matrix Perforated is designed to perform as a surgical mesh for soft tissue repair while presenting a scaffold for cellular and microvascular ingrowth. ARTIA Tissue Matrix Perforated consists of a terminally sterilized sheet of processed porcine dermal matrix provided in various geometric configurations and packaged in a plastic holder enclosed within a pouch. The device is sterilized via electron beam irradiation. The subject device has the same underlying scientific technology, principles of operation, Intended Use and Indications for Use as the cleared predicate device, ARTIA Tissue Matrix (K142326). This 510(k) premarket notification describes a new design feature of the subject device, which introduces a 3mm diameter circular pattern of perforations (holes) throughout the tissue matrix.

7.5 INDICATIONS FOR USE

ARTIA Tissue Matrix is intended for use as a soft tissue patch to reinforce soft tissue where weakness exists and for the surgical repair of damaged or ruptured soft tissue membranes which require the use of reinforcing or bridging material to obtain the desired surgical outcome. The implant is intended for reinforcement in plastic and reconstructive surgery.

ARTIA Tissue Matrix is intended for single patient, one time use only.

7.6 COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The subject and predicate devices are both surgical meshes derived from porcine dermis which undergo standardized, controlled manufacturing processes. Both devices consist of a terminally sterilized sheet of the processed porcine dermal matrix provided in various geometric configurations. The subject and the predicate devices share the same underlying scientific design and have the same Intended Use, Indications for Use and principles of operation and packaging configuration. Both are sterilized via electron beam irradiation.

The subject device includes a new design feature, 3mm diameter circular pattern of perforations (holes) in the tissue matrix. The spacing and size of the perforations were evaluated against the same established performance specifications as the predicate device, ARTIA Tissue Matrix (K142326). The subject device utilizes the existing manufacturing processes of the predicate ARTIA Tissue Matrix. Perforations are added to the tissue during the final die cutting stage at the time the device is cut to its final perimeter dimensions.

7.7 PERFORMANCE

The predicate device, ARTIA Tissue Matrix (K142326) has undergone appropriate biocompatibility assessments and testing, sterilization validation, and viral inactivation testing. The data demonstrates that the device is biocompatible and that the manufacturing process is capable of viral inactivation. The subject device, ARTIA Tissue Matrix Perforated and the predicate device, ARTIA Tissue Matrix (K142326) utilize the same raw materials (porcine dermis), processing components/solutions, and manufacturing processes, and are identical except for the presence of perforations. The only difference in the manufacturing process of the subject device is that during the final die cutting stage, perforations will be added to the tissue at the time the device is cut to its final perimeter dimensions. The cutting dies are provided sterilized from the vendor and utilize the same base materials, and the die cutting process is the same as the predicate device. The addition of holes in the product via die cutting does not change the material properties of the tissue. Therefore, no further biocompatibility testing or viral inactivation testing was performed.

Bench Testing:
Bench testing was performed to support substantial equivalence to the predicate device. Testing and/or evaluations included relevant elements of the FDA *"Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh"* issued March 2, 1999. ***Table 1*** includes the applicable product characterization criteria used to demonstrate substantial equivalence.

Table 1: Substantial Equivalence Criteria	
Bench Testing /Evaluation	Applicable Standard
Mesh Thickness	N/A
Tensile Strength	N/A
Device Stiffness	N/A
Suture Pull-Out Strength	N/A
Burst Strength	ASTM D6797-07(2011)
Tear Resistance	ASTM D5735-95

Performance data demonstrates that ARTIA Tissue Matrix Perforated has similar mechanical properties and meets the established specifications as the predicate device. In addition, the ARTIA Tissue Matrix Perforated Surgical Mesh shares the technological characteristics of perforations with LifeCell's other legally marketed reference device, Strattice Tissue Matrix Perforated (K150712). This new technological characteristic does not affect safety and efficacy of the device or raise new questions of safety or efficacy. ARTIA Tissue Matrix Perforated meets the requirements to perform its intended use as a soft tissue patch and is substantially equivalent to the predicate device, ARTIA Tissue Matrix (K142326).

Clinical Testing:
No clinical testing was included in this submission.

7.8 CONCLUSIONS

The subject device, ARTIA Tissue Matrix Perforated, meets the requirements to perform its intended use as a soft tissue patch and is substantially equivalent to the legally marketed predicate device, ARTIA Tissue Matrix (K142326).