



August 10, 2021

ACell, Inc.
% Salman Elmi, VP/Deputy General Counsel, Chief Compliance Officer
6640 Eli Whitney Drive
Columbia, MD 21046
Telephone: 410-953-8500
Email: salelmi4acell.com

Re: K141084

Trade/Device Name: Matristem Surgery Matrix RS, PSM, PSMX, Matristem Pelvic Floor Matrix
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: FTM, OXH

Dear Mr. Salman Elmi:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated June 17, 2015. Specifically, FDA is updating this SE Letter to remove the indications for use for transvaginal repair of pelvic organ prolapse from the SE package and labeling in accordance with FDA's final rule, dated January 5, 2016 in which such devices were upclassified from Class II to Class III.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Jason Roberts, OHT3: Office of Gastrorenal, ObGyn, General Hospital and Urology Devices, 240-402-6400, jason.roberts@fda.hhs.gov.

Sincerely,

Jason Roberts -S

Jason R. Roberts, Ph.D.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of Gastrorenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health



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

June 17, 2015

ACell Incorporated
Mr. Miles Grody
Senior Vice President, General Counsel
6640 Eli Whitney Drive, Suite 200
Columbia, Maryland 21046

Re: K141084

Trade/Device Name: MatriStem[®] Surgical Matrix RS, PSM, PSMX, and MatriStem[®]
Pelvic Floor Matrix

Regulation Number: 21 CFR 878.3300

Regulation Name: Surgical mesh

Regulatory Class: Class II

Product Code: FTM, OXH

Dated: June 16, 2015

Received: June 17, 2015

Dear Mr. Grody:

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" (21CFR 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 yours,

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

510(K) SUMMARY

Submission Date: July 6, 2018
Manufacturer Name:
Submitted by: ACell, Inc.
6640 Eli Whitney Drive
Columbia, MD 21046

Contact Person: Andrea Pilon Artman
Sr. Regulatory Affairs Manager
ACell, Inc.
Phone: (410) 953-8549
Email: andreaartman@acell.com
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DEVICE NAME AND CLASSIFICATION

510 (k) Number: K141084
Trade/Proprietary Name: MatriStem[®] Surgical Matrix RS, PSM, PSMX,
MatriStem[®] Pelvic Floor Matrix
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: ACell UBM Surgical Mesh (K040621)
ACell Surgical Mesh ML and ML Plus (K041140)
SIS Plastic Surgery Matrix (K034039)

DEVICE DESCRIPTION

MatriStem[®] Surgical Matrix RS, PSM, PSMX, and MatriStem[®] Pelvic Floor Matrix 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 pouches. The devices are terminally sterilized using electron beam irradiation.

INDICATIONS FOR USE

MatriStem[®] Surgical Matrix RS (2-layer) and PSM (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.

MatriStem[®] Surgical Matrix PSMX (6-layer) is 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.

MatriStem[®] Pelvic Floor Matrix (6-layer) is intended for implantation to reinforce soft tissue where weakness exists in patients requiring urological or gynecological surgery. Reinforcement of soft tissue within urological and gynecological surgery includes, but is not limited to, the following procedures: pubourethral support, urethral repair, transabdominal reconstruction of pelvic floor and vaginal prolapse, bladder support, and sacrocolposuspension. By providing pubourethral support, MatriStem Pelvic Floor Matrix may be used for the treatment of urinary incontinence resulting from urethral hypermobility and intrinsic sphincter deficiency.

EQUIVALENCE TO MARKETED DEVICES

MatriStem[®] Surgical Matrix RS, PSM, PSMX, and MatriStem[®] Pelvic Floor Matrix have the same intended use as predicate surgical meshes, which is to reinforce or repair soft tissue. The additional indications are identical to those included in the identified predicate devices. The technological characteristics of the MatriStem[®] Surgical Matrix RS, PSM, PSMX, and MatriStem[®] Pelvic Floor Matrix are substantially similar to the cleared predicates, as all are comprised of animal tissue-derived, collagen extracellular matrix (ECM) scaffolds supplied in a sheet configuration that are packaged and terminally sterilized. The available sizes of the subject device (8 – 150 cm²) are consistent with the range of sizes of the predicate devices (16 – 1350 cm²). The minor differences between the MatriStem[®] Surgical Matrix RS, PSM, PSMX, and MatriStem[®] Pelvic Floor Matrix and the identified predicates do not raise different questions of safety or efficacy and performance testing demonstrates that the devices have comparable performance to the predicates.

Biocompatibility Testing

MatriStem[®] Surgical Matrix RS, PSM, PSMX, and MatriStem[®] Pelvic Floor Matrix underwent the following biocompatibility testing on sterilized devices per ISO-10993-1 standard: 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 MatriStem[®] Surgical Matrix RS, PSM, PSMX, and MatriStem[®] Pelvic Floor Matrix meet biocompatibility requirements of the ISO standard.

Mechanical Testing

The MatriStem[®] Surgical Matrix RS, PSM, PSMX, and MatriStem[®] Pelvic Floor Matrix material were 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 MatriStem[®] Surgical Matrix RS, PSM, PSMX, and MatriStem[®] Pelvic Floor Matrix provide adequate mechanical strength for their respective applications.

CONCLUSION

Based on direct testing and comparison to predicate devices, MatriStem[®] Surgical Matrix RS, PSM, PSMX, and MatriStem[®] Pelvic Floor Matrix do not raise different questions of safety and effectiveness and the results support a determination of substantial equivalence through this 510(k) Premarket Notification.

Indications for Use

510(k) Number (if known)

K141084

Device Name

MatriStem Surgical Matrix RS, PSM, PSMX, and MatriStem Pelvic Floor Matrix

Indications for Use (Describe)

MatriStem Surgical Matrix RS (2-layer) and PSM (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.

MatriStem Surgical Matrix PSMX (6-layer) is 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.

MatriStem Pelvic Floor Matrix (6-layer) is intended for implantation to reinforce soft tissue where weakness exists in patients requiring urological or gynecological surgery. Reinforcement of soft tissue within urological and gynecological surgery includes, but is not limited to, the following procedures: pubourethral support, urethral repair, transabdominal reconstruction of pelvic floor and vaginal prolapse repair, bladder support, and sacrocolposuspension. By providing pubourethral support, MatriStem Pelvic Floor Matrix may be used for the treatment of urinary incontinence resulting from urethral hypermobility and intrinsic sphincter deficiency.

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)

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