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

June 12, 2017

TEI Biosciences, Inc
c/o Ms. Kavita Amin
Integra LifeSciences Corporation
311 Enterprise Drive
Plainsboro, New Jersey 08536

Re: K171357
Trade/Device Name: SurgiMend PRS Meshed, Revize-X
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: OXH, FTM
Dated: May 8, 2017
Received: May 9, 2017

Dear Ms. Amin:

This letter corrects our substantially equivalent letter of June 7, 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 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

Change Control Table, Change History

**Change Control Table**

| Version | Document Author | Document Approver | Date Approved |
|---|---|---|---|
| 1.00 | Name, Title, Office | Name, Title, Office | MM/DD/YYYY |

Complete Change Control Table (all versions) retained in SWIFT Docs.

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)*
K171357

Device Name
SurgiMend® Meshed Collagen Matrix for Soft Tissue Reconstruction

Indications for Use *(Describe)*

Indications For Use: SurgiMend® Meshed is intended for implantation to reinforce soft tissue where weakness exists and for surgical repair of damaged or ruptured soft tissue membranes. SurgiMend® Meshed is specifically indicated for plastic and reconstructive surgery.

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
## SurgiMend® Meshed Collagen Matrix for Soft Tissue Reconstruction

**Submitter's name and address:**

TEI Biosciences Inc.
7 Elkins Street
Boston, MA 02127 USA

**Contact person and telephone number:**

Kavita Amin
Specialist, Regulatory Affairs
Telephone: 609-373-7109

**Date the Summary was prepared:**

June 1, 2017

**Name of the device:**

| | |
|---|---|
| Trade name: | SurgiMend® PRS Meshed / Revize™-X Collagen Matrix for Soft Tissue Reconstruction |
| Common Name: | Surgical Mesh |
| Classification Name: | Mesh, Surgical (21 CFR 878.3300) |
| Product Code: | OXH, FTM |

**Predicate Device:**

SurgiMend Meshed is substantially equivalent in function and intended use to its predicate device as detailed in **Table 1**.

**Table 1:** Predicate Device

| 510(k) Number | Product Code | Trade Name | Manufacturer |
|---|---|---|---|
| K083898 | FTM | SurgiMend Collagen Matrix for Soft Tissue Reconstruction | TEI Biosciences Inc. |

**Device Description:**

SurgiMend Meshed is a meshed acellular dermal tissue matrix derived from bovine dermis. The device is supplied sterile in various sizes and designed to expand at a 2:1 ratio when hydrated with 0.9% saline.

**Indication for Use:**

SurgiMend Meshed is intended for implantation to reinforce soft tissue where weakness exists and for surgical repair of damaged or ruptured soft tissue membranes. SurgiMend Meshed is specifically indicated for plastic and reconstructive surgery.

**Substantial Equivalence Comparison:**

The modified device, SurgiMend Meshed, has the same manufacturing process as the predicate device, SurgiMend (K083898), with the addition of meshing, prior to packaging

and sterilization. The modified device, SurgiMend Meshed, is manufactured with the same material, material specification, processing steps and chemical composition as the predicate device, SurgiMend (K083898). The modified device adds a 2:1 fenestration pattern to the design of the predicate device, through a meshing process prior to packaging. The addition of a defined mesh in this new configuration allows the device to expand approximately 2-fold in area and to be more conformable during application.

**Testing and Test Results:**
The modified device, SurgiMend Meshed, is comprised of the same materials, processed, packaged and is sterilized by the same method as the predicate device (K083898). The biocompatibility testing conducted on the predicate device serves to confirm biocompatibility of the modified device, SurgiMend Meshed.

Performance testing for the modified device includes mechanical tests (burst strength, suture pull-out), conformability and differential scanning calorimetry (DSC) were conducted to be in compliance with FDA *Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh*, March 2, 1999. All test results were acceptable.

The modified device was characterized in a pre-clinical, acute/subacute animal model to evaluate the effect of meshing on the host biologic response after implantation. The study also evaluated implanted material histologically for revascularization and resorption/ remodeling of meshed (test) and solid (control) configurations. Gross, sub-gross and histological evaluation of explanted materials and surrounding tissues indicated no significant change in biological response with both materials exhibiting a bioreactivity score of Non-irritant in a modified ISO 10993-6 scoring system. The results of this study demonstrated that there were no significant differences between the predicate and modified device with respect to host biologic response and implant characteristics.

**Conclusion:**
The modified device, SurgiMend Meshed, is substantially equivalent to the commercially available marketed device, SurgiMend. The modifications expressed in this 510(k) Premarket Notification do not change the intended use, nor alter the fundamental scientific technology of the device. The modified device is as safe and as effective as the predicate device.