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

February 16, 2017

Integra LifeSciences Corporation
c/o Ms. Kavita Amin
Specialist, Regulatory Affairs
311 Enterprise Drive
Plainsboro, New Jersey 08536

Re: K162965
Trade/Device Name: SurgiMend MP Collagen Matrix for Soft Tissue Reconstruction
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: FTM
Dated: January 13, 2017
Received: January 17, 2017

Dear Ms. Amin:

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,

Jennifer R. Stevenson -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)*
K162965

Device Name
SurgiMend® MP Collagen Matrix for Soft Tissue Reconstruction

Indications for Use *(Describe)*
SurgiMend is intended for implantation to reinforce soft tissue where weakness exists and for surgical repair of damaged or ruptured soft tissue membranes.
SurgiMend is specifically indicated for:
• Plastic and reconstructive surgery
• Muscle flap reinforcement
• Hernia repair including abdominal, inguinal, femoral, diaphragmatic, scrotal, umbilical, and incisional hernias.

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

SurgiMend MP 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: 609-750-7827

Date the Summary was prepared: 13 January 2017

Name of the device:

Trade name:	SurgiMend® MP Collagen Matrix for Soft Tissue Reconstruction
Common Name:	Surgical Mesh
Classification Name:	Mesh, Surgical (21 CFR 878.3300)
Product Code:	FTM

Predicate Device:

SurgiMend® MP 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 is an acellular dermal tissue derived from bovine dermis. The device is available in solid, fenestrated, and perforated configurations. The device is supplied sterile in a variety of sizes, shapes, and thicknesses.

Indication for Use:

SurgiMend is intended for implantation to reinforce soft tissue where weakness exists and for surgical repair of damaged or ruptured soft tissue membranes:
SurgiMend is specifically indicated for:

- Plastic and reconstructive surgery
- Muscle flap reinforcement
- Hernia repair including abdominal, inguinal, femoral, diaphragmatic, scrotal, umbilical, and incisional hernias.

Substantial Equivalence Comparison:
The modified device, SurgiMend MP, utilizes the same design, material, manufacturing process, packaging and sterilization parameters as the predicate device (K083898). The proposed device, SurgiMend MP, is offered in perforated configuration with holes of 2-3 mm in diameter in a staggered array. The addition of defined holes in this new configuration allows for better fluid flow through the device upon implantation.

Testing and Test Results:
The modified device, SurgiMend MP, is comprised of the same materials, processed, packaged and sterilized by the same method as the predicate device (K083898). The biocompatibility testing conducted on SurgiMend Collagen Matrix for Soft Tissue Reconstruction (K083898) product confirms the biological safety of the SurgiMend MP.

Performance testing for SurgiMend MP is the same as the predicate device. Mechanical testing, including tensile strength, suture pull-out, tear resistance, and ball burst were conducted 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 implantation studies were conducted in three different animal models (12 week rat hernia repair study, 4 week rat intra-abdominal, 2 week rat intra-muscle implant model) with the primary endpoint of mechanical strength to support soft tissue reinforcement. The studies also characterized secondary endpoints of revascularization and tissue integration of perforated test and non-perforated control configurations. These studies demonstrate the basic properties of the subject device after implantation remain unchanged from the predicate. The result demonstrates the subject device is substantially equivalent to the predicate device.

Conclusion:
The modified device, SurgiMend MP, 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, and do not raise any new issues of safety and effectiveness.