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

Miromatrix Medical Inc.
% Miriam Provost, Ph.D.
Biologics Consulting Group, Inc.
400 N. Washington St., Suite 100
Alexandria, Virginia 22314

Re: K162570
Trade/Device Name: Miromatrix Biological Mesh TW
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: FTM, OWW
Dated: January 16, 2017
Received: January 18, 2017

Dear Dr. Provost:

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)*
K162570

Device Name
Miromatrix Biological Mesh TW

Indications for Use *(Describe)*
The Miromatrix Biological Mesh TW is indicated for the management and protection of tendon injuries in which there has been no substantial loss of tendon tissue.

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.

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In accordance with 21 CFR 807.87(h) and 21 CFR 807.92, the 510(k) Summary for the Miromatrix Biological Mesh TW is provided below.

1. SUBMITTER

Miromatrix Medical Inc.
10399 West 70th Street
Eden Prairie, MN 55334

Contact Person: Jeff Ross, Ph.D.
Phone: 763-458-8801
Email: jross@miromatrix.com
Date Prepared: September 13, 2016

2. DEVICE

510(k) Number: K162570
Name of Device: Miromatrix Biological Mesh TW
Common Name: Surgical Mesh
Classification Regulation: 21 CFR 878.3300
Regulatory Class: II
Product Code: FTM, OWW
Panel: General and Plastic Surgery

3. PREDICATE DEVICE

Predicate Device: Integra Tendon Wrap™ Tendon Protector (K053655)

Reference Device: Miromatrix Biological Mesh (K134033)

4. DEVICE DESCRIPTION

The Miromatrix Biological Mesh TW is an implantable, animal-sourced, acellular surgical mesh that is derived from porcine liver tissue. The liver tissue undergoes perfusion decellularization and the resulting mesh is comprised primarily of collagen type I. The Miromatrix Biological Mesh TW provides a scaffold during tissue repair and is designed to be an interface between the tendon and tendon sheath or the surrounding tissues. The Miromatrix Biological Mesh TW is designed for placement under, around or over the injured tendon. The device is terminally sterilized by electron beam irradiation in its packaging and is hydrated, moist and flexible when its packaging is opened. The mesh is available in sizes ranging from 1 cm x 2 cm to 10 cm x 20 cm, and may be trimmed or cut as required before being sutured to the surgical site.

5. INDICATION FOR USE

The Miromatrix Biological Mesh TW is indicated for the management and protection of tendon injuries in which there has been no substantial loss of tendon tissue.

This indication for use is identical to that of the predicate device, the Integra Tendon Wrap™ Tendon Protector (K053655).

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The similarities and differences in technological characteristics between the subject Miromatrix Biological Mesh TW and the predicate mesh are summarized below.

6.1. Similarities

The Miromatrix Biological Mesh TW is similar in design to the predicate Integra Tendon Wrap™ Tendon Protector (K053655). Both are designed to provide a protective environment while the tendon is healing for the management and protection of the tendon injuries in which there has been no substantial loss of tendon tissue.

In addition, the Miromatrix Biological Mesh TW is identical in materials (i.e., porcine liver tissue) to the reference device, the Miromatrix Biological Mesh (K134033).

6.2. Differences

Although similar in design, there are minor differences in dimensions between the subject Miromatrix Biological Mesh TW and the predicate Integra Tendon Wrap™ Tendon Protector (K053655). The Miromatrix Biological Mesh TW has a thickness of 0.1-1.5 mm and sizes from 1x2 cm to 10x20 cm. Based on Miromatrix's own measurements, the predicate Integra Tendon Wrap™ Tendon Protector has a thickness range that slightly exceeds that of the subject device. Based on publically available information, the sizes of the predicate are similar, i.e., 5x5cm and 10x12.5cm.

When compared to the reference device (i.e., the Miromatrix Biological Mesh of K134033), the only difference in design are a slight change in dimensions, i.e., a reduction in the mesh thickness (i.e., from 0.5-3 mm to 0.1-1.5 mm) and a reduction in the maximum mesh size (i.e., from 20x30 cm to 10x20 cm).

In terms of materials, the predicate Integra Tendon Wrap™ Tendon Protector is comprised of a porous matrix of cross-linked bovine Type I collagen and glycosanminoglycan (GAG). While the predicate material is different from the porcine liver tissue that comprises the subject device, the difference does not raise a new question of safety and effectiveness.

The subject device has the same material as the reference device (K134033). Thus, the biocompatibility of the subject device material (i.e., porcine liver) and, therefore, its safety for the proposed intended use has already been established as part of K134033.

7. PERFORMANCE DATA

Because the materials of the subject Miromatrix Biological Mesh TW are identical to that of the reference device, the Miromatrix Biological Mesh (K134033), no new biocompatibility testing is required to demonstrate substantial equivalence.

Shelf life testing was performed to establish the proposed shelf life of the device.

Bench and animal data show that the subject Miromatrix Biological Mesh TW is substantially equivalent to the predicate Integra Tendon Wrap™ Tendon Protector with regard to performance. Specifically:

- The total tensile strength and suture pullout strength were evaluated and measured for both the Miromatrix Biological Mesh TW and the predicate device. The Miromatrix Biological Mesh TW was shown to have higher tensile and suture pullout strength than the predicate device. These differences do not have any impact on safety and effectiveness, and therefore, on substantial equivalence.
- Animal testing comparing the subject and predicate devices in a 4 and 10-week partial Achilles tendon defect model was performed. After 4 and 10 weeks, the average tissue attachment was comparable. The healing response at 4 and 10 weeks was also comparable.

8. CONCLUSIONS

The Miromatrix Biological Mesh TW is identical in indications to the predicate Integra Tendon Wrap (K053655).

The Miromatrix Biological Mesh TW is similar in design to the predicate Integra Tendon Wrap (K053655). In terms of materials, the Integra Tendon Wrap is comprised of a porous matrix of cross-linked bovine Type I collagen and glycosanminoglycan (GAG). While the Integra Tendon Wrap material is different from the porcine liver tissue that compromises the subject device, the difference does not raise a new question of safety and effectiveness. The biocompatibility of the subject device material (i.e., porcine liver) has already been established as part of K134033.

Performance testing (bench and animal testing) of the subject device versus the predicate device was performed and the results demonstrate that the subject device is substantially equivalent to the predicate device for the proposed indication for use.

In conclusion, based on the exact same indication for use and comparable design and performance to the predicate Integra Tendon Wrap (K053655) and based on the same materials and comparable design to the reference device Miromatrix Biological Mesh (K134033), as well as favorable preclinical testing, the subject Miromatrix Biological Mesh TW may be found substantially equivalent.