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 8, 2016

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

Re: K160400
Trade/Device Name: Miromatrix Biological Mesh
Regulation Number: 21 CFR 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: OXH, FTM
Dated: May 12, 2016
Received: May 13, 2016

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 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

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)*
K160400

Device Name
Miromatrix Biological Mesh

Indications for Use *(Describe)*
The Miromatrix Biological Mesh is intended to be implanted to reinforce soft tissue and is also intended for implantation to reinforce soft tissue where weakness exists in patients requiring soft tissue repair or reinforcement in 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.

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 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: February 10, 2016

2. DEVICE

Name of Device: Miromatrix Biological Mesh
Common Name: Surgical Mesh
Classification Regulation: 21 CFR 878.3300
Regulatory Class: II
Product Code: OXH and FTM
Panel: General and Plastic Surgery

3. PREDICATE DEVICE

Predicate Device: Miromatrix Biological Mesh (cleared as Miromatrix Biological Mesh RS), K150341

Reference Device: K134033, Miromatrix Biological Mesh

4. DEVICE DESCRIPTION

The Miromatrix Biological Mesh 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 device is intended to function as a surgical mesh for soft tissue repair while providing a scaffold for tissue incorporation. The device is terminally sterilized 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 20 cm x 30 cm, and may be trimmed or cut as required before being sutured to the surgical site.

5. INDICATIONS FOR USE

The Miromatrix Biological Mesh is intended to be implanted to reinforce soft tissue and is also intended for implantation to reinforce soft tissue where weakness exists in patients requiring soft tissue repair or reinforcement in plastic and reconstructive surgery.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

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

6.1. Similarities

The subject and the predicate device are identical with regard to indication for use, design, manufacturing, sterilization, packaging, and shelf life. The proposed and predicate device have the same range of sizes of the individual mesh, the same mesh thickness range, and the same origin and processing of the source material

6.2. Differences

The difference between the subject and predicate device is a change to the labeling (Instructions for Use). Specifically, the labeling has been modified to provide instructions for physicians to quilt two or more meshes together when deemed clinically necessary. The quilting is being performed solely by the physician and not Miromatrix (i.e., no changes have been made to the device as a result of this labeling change).

These differences in the labeling do not raise a new question of safety and effectiveness because there is no change in the mesh product that is manufactured by Miromatrix, and the risk analysis showed that quilted mesh met the pre-determined acceptance criteria for the individual cleared mesh.

7. PERFORMANCE DATA

In support of this Special 510(k), a risk analysis was performed. The potential risks introduced by quilting of two or more meshes together were identified per ISO 14971:2007 Medical devices – Application of risk management to medical devices. The risk analysis method used was Failure Modes Effect Analysis (FMEA). Using this risk analysis method, Miromatrix identified the risks and verification and validation activities were performed to demonstrate that the quilted device meets the pre-determined acceptance criteria.

8. CONCLUSIONS

The only difference between the subject and predicate device is a change to the labeling (Instructions for Use). Specifically, the labeling has been modified to provide instructions for physicians to quilt two or more meshes together when deemed clinically necessary. The quilting is being performed solely by the physician and not Miromatrix (i.e., no changes have been made to the device as a result of this labeling change).

Quilting does not alter the fundamental scientific technology of the device. The verification and validation activities met the pre-determined acceptance criteria were met.

In conclusion, the subject Miromatrix Biological Mesh with modified labeling is substantially equivalent to the predicate device cleared under K150341.