MAR 3 1 2014

5. 510(K) SUMMARY

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.

Device Common Name: Surgical Mesh

Device Proprietary Name: Miromatrix Biological Mesh

Submitter:
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Eden Prairie, MN 55347
www.miromatrix.com

Contact:
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Biologics Consulting Group, Inc.
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Miromatrix Medical, Inc.
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Date Prepared: December 30, 2013

Classification Regulation: 21 CFR 878.3300

Panel: General & Plastic Surgery

Product Code: FTM

Predicate Device: K980431, SurgiSIS Surgical Mesh
Cook Biotech, Inc.

Indication for Use:
The Miromatrix Biological Mesh is intended to be implanted to reinforce soft tissue.

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 Miromatrix Biological Mesh 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.

Comparison to the Predicate:
The Miromatrix Biological Mesh has similar indications for use and technological characteristics as the predicate surgical mesh. Both devices are porcine-derived, acellular meshes that are comprised primarily of collagen type I. The meshes reinforce soft tissue while providing a scaffolding for tissue repair.

Mechanical testing, biocompatibility testing and animal testing were conducted per the recommendations in: *Guidance for Industry and/or for FDA Reviewers/Staff and/or Compliance – Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh," dated March 2, 1999.*" The following tests were conducted:

Biocompatibility Testing
In Vitro Cytotoxicity
Skin Sensitization (Maximization Method)
Intracutaneous Reactivity
Acute Systemic Toxicity
In Vitro Bacterial Reverse Mutation (AMES)
In Vitro Chromosome Aberration
In Vitro Mammalian Cell Gene Mutation
Intramuscular Implantation
In Vitro Hemolysis
Pyrogenicity
Sub-Chronic Systemic Toxicity

Bench/Laboratory Testing
Tensile Strength
Suture Retention Strength
Burst Force
Tear Resistance
DNA Residuals
Collagen Analysis

Viral Inactivation
Endotoxin
Expiration Dating

Animal Testing
30-Day Rat Implantation Study

The biocompatibility testing showed the comparable safety profile of the Miromatrix Biological Mesh and the predicate. Bench testing demonstrated that the mechanical properties of the mesh are substantially equivalent for reinforcing soft tissue. Animal testing demonstrated tissue incorporation into the mesh.

Summary of Substantial Equivalence:
Based on the indications for use, technological characteristics and performance test results, the Miromatrix Biological Mesh is substantially equivalent to the predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

March 31, 2014

Miromatrix Medical, Inc.
c/o Biologics Consulting Group, Inc.
Stephen P. Rhodes
400 North Washington Street, Suite 100
Alexandria, Virginia 22314

Re: K134033
Trade/Device Name: Miromatrix Biological Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: FTM
Dated: December 31, 2013
Received: December 31, 2013

Dear Mr. Rhodes:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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 Ashar, MD, MBA, FACS
Acting 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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K134033

Device Name
Miromatrix Biological Mesh

Indications for Use *(Describe)*

The Miromatrix Biological Mesh is intended to be implanted to reinforce soft 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Jiyoung Dang -S