MLM Biologics Inc.

JUL 2 2 2014

510(k) Summary

bio-ConneKt Wound Matrix (K140456)

Date: June 3, 2014

Submitted by: MLM Biologics
12085 Research Drive
Alachua, FL 32615

Representative: Gregg Ritter, MS, RAC
RA/QA Manager
Phone: 352.494.2122
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Proprietary Name: bio-ConneKt Wound Matrix

Common Name: Collagen Wound dressing

Classification: Unclassified

Classification Code: KGN

Predicate Devices:

Trade/Proprietary Name	Manufacturer	510(k) Number
Biopad®	Euroresearch S.R.L.	K040283
Collagen Wound Dressing	Dalim Tissen Co.	K112580
Integra Matrix Wound Dressing (AVAGEN)	Integra LifeSciences Corp.	K022127

Description: The bio-ConneKt Wound Matrix is a sterile, conformable and porous wound dressing made of reconstituted collagen derived from equine tendon. It is chemically crosslinked to provide resistance to enzymatic degradation. The dressing is provided sterile for single use only.

Indications for Use: The MLM Biologics bio-ConneKt Wound Matrix is a collagen-based wound dressing for the local management of moderately to heavily exuding wounds, including:

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- Partial and full thickness wounds
- Draining wounds
- Tunneling wounds
- Pressure sores/ulcers
- Venous ulcers
- Chronic vascular ulcers
- Diabetic ulcers
- Trauma wounds (e.g., abrasions, lacerations, partial thickness burns, skin tears)
- Surgical wounds (e.g., donor sites/grafts, post-laser surgery, post-Mohs' surgery, podiatric wounds, dehisced surgical incisions)

Technological Characteristics:

The bio-ConneKt Wound Matrix is similar in materials and design to the predicate devices. The device consists of Type 1 collagen that has been extracted from animal tissue, crosslinked and sterilized. The only differences in to the predicate devices are given below:

Biopad – not crosslinked
Dalim Tissen Collagen Wound Dressing – composed of two-layer highly purified porcine skin collagen
Integra Matrix Wound Dressing – composed of bovine tendon collagen and glycosaminoglycan, glutaraldehyde crosslinker

These differences raise no concerns regarding the potential safety of effectiveness of the applicant device.

Performance Tests:

Biocompatibility testing and *in vitro* bench testing have been conducted to evaluate the biological safety and characteristics of the bio-ConneKt Wound Matrix. No clinical testing was performed. Biocompatibility testing was performed under Good Laboratory Practices (GLP) accordance with the relevant parts of ISO 10993 Biological Evaluation of Medical Devices. All GLP testing met the criteria for biocompatibility. The testing criteria followed were based on the following medical device categorization: surface device, breached or compromised surface, >30 days contact duration. Tests were done in the following categories: cytotoxicity, sensitization, intracutaneous reactivity, systemic toxicity (acute, sub-acute, sub-chronic) and genotoxicity.

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Results of an appropriate implantation study support the biocompatibility of bio-ConneKt Wound Matrix as compared to a predicate device control.

Sterilization: bio-ConneKt Wound Matrix is radiation (E-beam) sterilized to provide a sterility assurance level of 10^{-6}.

Conclusion: bio-ConneKt Wound Matrix is substantially equivalent to the predicate devices in design, material, and indications for use. From the results of non-clinical testing presented in this application MLM Biologics concludes that the bio-ConneKt Wound Matrix is as safe, as effective and performs as well as or better than the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 22, 2014

MLM Biologics
Mr. Gregg Ritter, MS, RAC
Regulatory Affairs/Quality Assurance Manager
12085 Research Drive
Alachua, Florida 32615

Re: K140456
Trade/Device Name: bio-ConneKt Wound Matrix
Regulatory Class: Unclassified
Product Code: KGN
Dated: June 3, 2014
Received: June 4, 2014

Dear Mr. Ritter:

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

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)*
K140456

Device Name
bio-ConneKt Wound Matrix

Indications for Use *(Describe)*
The MLM Biologics bio-ConneKt Wound Matrix is a collagen-based wound dressing for the local management of moderately to heavy exuding wounds, including:

- Partial and full thickness wounds
- Draining wounds
- Tunneling wounds
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- Chronic vascular ulcers
- Diabetic ulcer
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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

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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