December 15, 2022

Engineered Tissue Solutions, LLC
% Mr. Randy Prebula
Partner
Hogan Lovells US, LLP
555 Thirteenth Street, Northwest
Washington, District of Columbia 20009

Re: K161067
Trade/Device Name: Mirragen™ Advanced Wound Matrix
Regulatory Class: Unclassified
Product Code: QSZ

Dear Mr. Randy Prebula:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated September 15, 2016. Specifically, FDA is updating this SE Letter because FDA has better categorized your device technology under product code QSZ.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Julie Morabito, OHT4: Office of Surgical and Infection Control Devices, 240-402-3839, Julie.Morabito@fda.hhs.gov.

Sincerely,

Julie A. Morabito -S

Julie Morabito, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

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

September 15, 2016

Engineered Tissue Solutions, LLC
% Mr. Randy Prebula
Partner
Hogan Lovells US, LLP
555 Thirteenth Street, Northwest
Washington, District of Columbia 20009

Re: K161067
Trade/Device Name: Mirragen™ Advanced Wound Matrix
Regulatory Class: Unclassified
Product Code: FRO
Dated: August 19, 2016
Received: August 19, 2016

Dear Mr. Randy Prebula:

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)*
K161067

Device Name
Mirragen™ Advanced Wound Matrix

Indications for Use *(Describe)*
The Mirragen™ Advanced Wound Matrix is intended for use in the management of wounds. Wound types include: Partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/ undermined wounds, surgical wounds (donor sites/grafts, post-Moh's surgery, post laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, first and second degree burns, skin tears) and draining wounds.

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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Food and Drug Administration
Office of Chief Information Officer
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PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY
K161067

1. Submitter Information:

Engineered Tissue Solutions, LLC
4030 Hypoint North
Rolla, MO 65401
Phone: (573)-458-5966
Fax: (573)-755-0588
Contact Person: Mark Borden, Ph.D.

Date Prepared: September 15, 2016

2. Contact Information:

Randy Prebula
Hogan Lovells U.S., LLP
555 Thirteenth Street, NW
Washington, DC 20004

3. Device Name and Classification:

Trade/Proprietary Name:	Mirragen™ Advanced Wound Matrix
Common/Usual Name:	Wound dressing
Classification Name:	Unclassified
Classification Panel:	General and Plastic Surgery
Product Code:	FRO (Dressing, Wound, Drug)
Device Class:	Unclassified

4. Predicate Devices

- Medline Industries, Inc. Puracol® Plus Ag+ MicroScaffold™ Wound Dressing (K071552)
- W.L. Gore & Associates, Inc. GORE® BIO-A® Wound Matrix (K132397)

5. Intended Use / Indications for Use

The Mirragen™ Advanced Wound Matrix is intended for use in the management of wounds. Wound types include: Partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds (donor sites/grafts, post-Moh's surgery, post laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, first and second degree burns, skin tears) and draining wounds.

6. Device Description

The Mirragen™ Advanced Wound Matrix is composed solely of biocompatible and resorbable borate glass fibers and particulate. The borate glass constituent is medical-grade. The device is a resorbable fiber dressing that covers the wound. It may be used for a period of 3 to 7 days. The porosity of the device allows for absorption of fluid.

7. Performance Data

The company performed a variety of preclinical testing to support the safety and effectiveness of the Mirragen™ Advanced Wound Matrix for its intended use. This testing is described in full in the 510(k) submission, and is summarized below.

For characterization of the dressing, the volume, mass, and density of samples of the Mirragen™ dressing were first measured and recorded. Samples were also subjected to various functional tests, including X-ray fluorescence spectroscopy for composition analysis, X-ray diffraction to analyze the product's crystallinity, and physical manipulation (cutting and handling) to assess friability, durability, and ease of use. Further structural characterization was performed through SEM imaging and analysis that evaluated the distributions of fiber sizes and particle sizes in the dressing. In addition, the company measured weight loss from samples incubated in 37°C water at various time points, which established the dressing's 45-day aqueous dissolution time, and measured the weight of the dressing before and after fluid saturation to determine the fluid absorption capacity. Results showed that the device meets its specifications, which are similar to those of the predicate devices that have similar resorbable fiber structures. In all instances, the Mirragen™ dressing functioned as intended and the qualities observed were as expected.

The dressing was also tested against the predicate devices in full and partial thickness wounds in a clinically relevant porcine model. Wound healing analyses included macroscopic assessment of wound healing, planimetric measurement of wound closure, histopathology, and histomorphometry. Test results showed that the Mirragen™ Advanced Wound Matrix and the predicate devices had a similar wound healing response and exhibited no adverse tissue responses.

In accordance with ISO 10993, the company conducted the biocompatibility tests recommended for a surface device that is in prolonged contact with breached or compromised skin. This included tests for cytotoxicity, sensitization, and irritation/intracutaneous reactivity. The company also conducted additional tests per ISO 10993 to supplement the biocompatibility evaluation of the Mirragen™ dressing, including sub-acute toxicity and a variety of genotoxicity tests (Ames, chromosomal aberration, and erythrocyte micronucleus). All results were passing, demonstrating the biocompatibility of the Mirragen™ Advanced Wound Matrix.

8. Substantial Equivalence

The Mirragen™ Advanced Wound Matrix is as safe and effective as the Puracol® Plus Ag+ MicroScaffold™ Wound Dressing and the GORE® BIO-A® Wound Matrix. The subject device has the same intended use and similar indications, technological characteristics, and principles of operation as its predicate devices. The minor technological differences between the Mirragen™

Advanced Wound Matrix and its predicate devices raise no different questions of safety or effectiveness. Performance data further support the product's safety and effectiveness in comparison to the predicates. Thus, the Mirragen™ Advanced Wound Matrix is substantially equivalent.

9. Conclusions

The Mirragen™ Advanced Wound Matrix has similar structure and principles of operation as the cleared predicate devices; bench and animal testing further support that the device performs as intended. Thus, the device is substantially equivalent to the predicate devices.