April 21, 2021

Triad Life Sciences, Inc.
% Stephen Rhodes
Regulatory Consultant
Streamline Regulatory
3502 Dundee Driveway
Chevy Chase, Maryland 20815

Re: K210580
Trade/Device Name: InnovaMatrix FS
Regulatory Class: Unclassified
Product Code: KGN
Dated: February 25, 2021
Received: February 26, 2021

Dear Stephen 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Lixin Liu, Ph.D.
Acting 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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210580

Device Name
InnovaMatrix™ FS

Indications for Use *(Describe)*
InnovaMatrix™ FS is indicated for the management of wounds including:

- Partial and full-thickness wounds
- Pressure ulcers
- Venous ulcers
- Diabetic ulcers
- Chronic vascular ulcers
- Tunneled/undermined wounds
- Surgical wounds (donor sites/grafts, post-Mohs surgery, post- laser surgery, podiatric, wound dehiscence)
- Trauma wounds (abrasions, lacerations, second-degree burns and skin tears)
- Draining wounds

The device is intended for one-time use.

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.

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510(k) Summary – K210580

In accordance with 21 CFR 807.87(h) and 21 CFR 807.92, the Special 510(k) Summary is provided below.

1. SUBMITTER

Triad Life Sciences®, Inc.
1770 Moriah Woods Blvd., Suite 18
Memphis, TN 38117
Registration Number: 3017660750

Contact Person: William J. Willis
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Email: bwillis@triadls.com

Prepared By: Stephen P. Rhodes, Streamline Regulatory stephen.rhodes@streamlineregulatory.com
Date Prepared: April 21, 2021

2. DEVICE

Name of Device: InnovaMatrix™ FS
Common Name: Collagen Wound Dressing
Classification Regulation/Class: Unclassified
Product Code: KGN
Panel: General and Plastic Surgery

3. PREDICATE AND REFERENCE DEVICE

Predicate Device: InnovaMatrix™ (K193552)
Reference Device: Oasis® Wound Matrix (K061711)

4. DEVICE DESCRIPTION

Description

InnovaMatrix™ FS is a decellularized extracellular matrix (ECM) topical wound covering derived from porcine placental tissue. Triad processes the tissue into the ECM topical wound covering. InnovaMatrix™ FS is composed of collagen, elastin, laminin, fibronectin, hyaluronic acid and sulfated glycosaminoglycans. The wound dressing is provided in fenestrated sheets that are approximately 40-100 microns thick in sizes ranging from 2 x 2cm to 5 x 5cm. They are provided as single-use, sterile wound coverings.

5. INDICATION FOR USE

InnovaMatrix™ FS is indicated for the management of wounds including: partial- and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled / undermined wounds, surgical wounds (donor sites/grafts, post Mohs surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, second-degree burns and skin tears) and draining wounds.
The device is intended for one-time use.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

InnovaMatrix™ FS is a decellularized extracellular matrix (ECM) topical wound covering derived from porcine placental tissue. Triad processes the tissue into the ECM topical wound coverings. InnovaMatrix™ FS is composed of collagen, elastin, laminin, fibronectin, hyaluronic acid and sulfated glycosaminoglycans. The biodegradable wound matrix provides a protective cover to the wound.

The only modification made to the device since its previous clearance in K193552 is the addition of fenestrations.

Table 1 provides a summary comparison between the subject and predicate devices.

Table 1: Device Comparison Table

	Subject Device	Predicate Device
510(k) Number	TBD	K193552
Applicant	Triad Life Sciences, Inc.	Triad Life Sciences, Inc.
Device Name	InnovaMatrix™ FS	InnovaMatrix™
Regulation/Class	Unclassified Collagen Wound Dressing	Unclassified Collagen Wound Dressing
Product Code	KGN	KGN
Prescription or OTC?	Prescription	Prescription
Indications for Use	InnovaMatrix™ FS is indicated for the management of wounds including: partial- and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds (donor sites/grafts, post-Mohs surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, second-degree burns and skin tears) and draining wounds.	same
Design	Single layer, porcine extracellular matrix from placenta (fenestrated)	Single layer, porcine extracellular matrix from placenta
Sizes	2 x 2 cm, 4 x 4 cm, 5 x 5 cm	1 x 1 cm to 5 x 5 cm
Thickness	40-100 microns	same
Single Use?	Yes	same
Sterile	E-Beam-sterilized	same

Overall, the difference in technological characteristics of the subject and predicate device, i.e., the addition of fenestrations, does not raise any different questions of safety and effectiveness.

7. PERFORMANCE DATA

Verification testing was conducted to confirm that bioburden, endotoxin and water absorption capacity were within the specified values in accordance with the risk assessment.

As InnovaMatrix™ FS is comprised of the same materials and undergoes the same manufacturing processing steps with the inclusion of the creation of the fenestrations, existing biocompatibility, shelf life, sterilization, human repeat insult patch testing and human skin prick testing for the predicate InnovaMatrix™ remains applicable to InnovaMatrix™ FS.

8. CONCLUSIONS

InnovaMatrix™ FS has the identical indications for use as the predicate device InnovaMatrix™. The technological characteristics are similar to the technological characteristics of the predicate wound dressing. The only modification for the subject device is the addition of fenestrations to the predicate device. The fenestrations of the subject device are features of the reference device, Cook Biotech's OASIS® Wound Matrix. The reference device has the same indications for use as the subject device. Both the predicate and subject devices are placental porcine-derived, decellularized dressings that are comprised primarily of collagen. The dressings are both intended for the management of wounds. Based on the indications for use, technological characteristics, and performance test results, InnovaMatrix™ FS is substantially equivalent to the predicate device InnovaMatrix™ (K193552). In addition, the Design Controls demonstrates that the modified device met the pre-determined acceptance criterion for the verification activity to substantiate the addition of fenestrations to the wound dressing.