October 21, 2020

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

Re: K193552
Trade/Device Name: InnovaMatrix™
Regulatory Class: Unclassified
Product Code: KGN
Dated: September 24, 2020
Received: September 24, 2020

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,

Kimberly M. Ferlin, Ph.D.
Assistant Director (Acting)
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193552

Device Name
InnovaMatrix™

Indications for Use *(Describe)*
InnovaMatrix™ 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.

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 is provided below.

1. SUBMITTER

Triad Life Sciences, Inc.
1770 Moriah Woods Blvd., Suite 18
Memphis, TN 38117

Contact Person: Russell I. Olsen
Phone: 901-333-6000
Email: rolsen@triadls.com

Prepared By: Stephen P. Rhodes, Streamline Regulatory
stephen.rhodes@streamlineregulatory.com
Date Prepared: October 21, 2020

2. DEVICE

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

3. PREDICATE DEVICE

Predicate Device: Oasis Wound Matrix (K061711)

4. DEVICE DESCRIPTION

Description
InnovaMatrix™ 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™ is composed of collagen, elastin, laminin, fibronectin, hyaluronic acid and sulfated glycosaminoglycans.

The wound dressing is provided in sheets that are approximately 40-100 microns thick in sizes ranging from 1 x 1cm to 5 x 5cm. They are provided as single-use, sterile wound coverings.

5. INDICATION FOR USE

InnovaMatrix™ 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™ 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™ is composed of collagen, elastin, laminin, fibronectin, hyaluronic acid and sulfated glycosaminoglycans. The biodegradable wound matrix provides a protective cover to the wound.

The predicate Oasis Wound Matrix is an ECM topical wound covering derived from porcine small intestinal submucosal tissue. The predicate ECM is composed of collagen, elastin, laminin, fibronectin, hyaluronic acid and glycosaminoglycans. Like the subject device, the collagen-glycosaminoglycan biodegradable matrix provides a protective cover to the wound.

Overall, the differences in technological characteristics of the subject and predicate device do not raise any different questions of safety and effectiveness.

7. PERFORMANCE DATA

The following GLP compliant, biocompatibility studies were conducted to evaluate the safety of the InnovaMatrix™:

<u>Biocompatibility Testing</u>

- In Vitro Cytotoxicity
- Skin Sensitization (Maximization Method)
- Intracutaneous Reactivity
- Acute Systemic Toxicity
- Subacute Toxicity
- Implantation: 1-week, 2-week, 4-week and 13-week
- In Vitro Bacterial Reverse Mutation (AMES)
- Mouse Lymphoma Assay
- Sub-Chronic Systemic Toxicity
- Material-Mediated Pyrogenicity

The biocompatibility testing showed the comparable safety profile of InnovaMatrix™ and the predicate.

Per FDA guidance on shelf life, sterilization, and devices containing animal-derived material, the following laboratory and clinical studies were also conducted:

Laboratory Testing

- Cell Debris
- Collagen Analysis
- Elastin, hyaluronic acid, laminin, fibronectin, nucleic acid and sulfated glycosaminoglycan analysis
- Endotoxin
- Residual Moisture
- Water Absorption
- Ultimate Tensile Strength and Tensile Modulus
- Viral Inactivation
- Expiration Dating / Shelf Life for Two Month Shelf Life
- Heavy Metals Residuals Testing per FDA Q3D(R1) Elemental Impurities Guidance for Industry (March 2020), including Class 1 Elements; Class 2A Elements; and Applicable Class 3 Elements [Li (lithium), Sb (antimony), and Cu (copper)]

Clinical Testing

- Human Repeat Insult Patch Testing
- Human Skin Prick Testing

Human Repeat Insult Patch Testing and Skin Prick Testing was performed. 58 subjects completed the Human Repeat Insult Patch Testing with no reactions. 23 subjects completed the Skin Prick Testing with 22 subjects exhibiting no reactions. One of the 23 subjects had a low-grade positive reaction at the 15 minute timepoint which resolved to no reaction at the 6 hour and 24-48 hour timepoints.

8. CONCLUSIONS

InnovaMatrix™ has the identical indications for use as the predicate device. The technical characteristics are similar to the technological characteristics of the predicate wound dressing. Both devices are 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™ is substantially equivalent to the predicate device (K061711).