September 28, 2022

Donna Best
Chief Operating Officer
1770 Moriah Woods Blvd, Suite 18
Memphis, Tennessee 38117

Re: K211902
Trade/Device Name: InnovaMatrix PD
Regulatory Class: Unclassified
Product Code: KGN
Dated: March 15, 2022
Received: March 15, 2022

Dear Donna Best:

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,

For 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

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)*
K211902

Device Name

InnovaMatrix PD

Indications for Use *(Describe)*
InnovaMatrix PD 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, and skin tears), draining wounds, and partial-thickness burns

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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Traditional 510(k) Summary – K211902

In accordance with 21 CFR Part 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
Registration Number: 3017660750

Contact Person: Donna Best
Phone: (901) 333-6000
Email: dbest@triadls.com

Prepared By: Donna Best
Date Prepared: September 19, 2022

2. DEVICE

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

3. PREDICATE AND REFERENCE DEVICE

Predicate Device: Cook® ECM Powder (K152033)
Reference Device: InnovaMatrix® (K193552)

4. DEVICE DESCRIPTION

Description
InnovaMatrix® PD is a powder manufactured from the decellularized extracellular matrix (ECM) derived from porcine placental tissue harvested according to Good Manufacturing Practices. Further treatment and final sterilization yield a particulate device prepared for the management of wounds. The particulate is meant to be deployed by the user to manage wounds of the types outlined in the Indications for Use of the device.
InnovaMatrix® PD is composed of collagen, elastin, laminin, fibronectin, hyaluronic acid and sulfated glycosaminoglycans.
The wound dressing is provided in a particulate form as a single-use, sterile wound covering.

5. INDICATION FOR USE

InnovaMatrix® PD 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, and skin tears), draining wounds and partial-thickness burns.
The device is intended for one-time use.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Similar to the predicate Cook® ECM Powder, InnovaMatrix® PD is an extracellular matrix (ECM) topical wound covering in particulate form, derived from porcine material. The biodegradable wound powder provides a protective cover to the wound.

The predicate Cook® ECM Powder (K152033) is an animal-sourced wound dressing that is derived from porcine small intestinal submucosa (SIS). The porcine SIS, and the resulting wound dressing, is comprised of primarily Types I, III, IV and VI collagen (constituents of the extracellular matrix). The device is intended for use in the management of wounds. Cook® ECM Powder is terminally sterilized in its packaging, applied dry, and becomes hydrated and moist during use. The Cook® ECM Powder is provided in particulate form with particles of ≤1000 µm.

Similar to the predicate Cook® ECM Powder, InnovaMatrix® PD is also composed primarily of collagen. InnovaMatrix® PD is chemically identical to the InnovaMatrix® reference device and differs only in physical form (particulate versus sheet). The device is intended for use in the management of wounds. InnovaMatrix® PD is terminally sterilized in its packaging, applied dry, and becomes hydrated and moist during use.

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

Summary of Technological Characteristics

	Subject Device InnovaMatrix® PD Particulate Form 510(k) Clearance: K211902	Predicate Device Cook® ECM Powder Particulate Form 510(k) Clearance: K152033	Reference Device InnovaMatrix® Sheet Form 510(k) Clearance: K193552
Product Code	KGN	KGN	KGN
Classification	Dressing, Wound, Collagen	Dressing, Wound, Collagen	Dressing, Wound, Collagen
Intended Use	Wound Management 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, and skin tears), draining wounds and partial-thickness burns	Wound Management 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	Wound Management 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
Material	Porcine Placenta	Porcine Small Intestinal Submucosa (SIS)	Porcine Placenta
Material Type	Collagen, Extracellular Matrix	Collagen, Extracellular Matrix	Collagen, Extracellular Matrix
Use	Single use	Single use	Single use

	Subject Device InnovaMatrix® PD Particulate Form 510(k) Clearance: K211902	Predicate Device Cook® ECM Powder Particulate Form 510(k) Clearance: K152033	Reference Device InnovaMatrix® Sheet Form 510(k) Clearance: K193552
Sterilization	E-Beam Irradiation	Ethylene Oxide	E-Beam Irradiation
Sizes	Particles ≤ 1000 µm	Particles ≤ 1000 µm	1cm x 1cm to 5cm x 5cm
Additional Feature(s)	Mass offering up to ≤ 200 mg	Mass offering up to ≤ 1000 mg	Solid Sheet, 4 sheets/application

7. PERFORMANCE DATA

Summary of the Non-Clinical Tests:

The following testing was performed to mitigate any risk posed by the additional processing steps and change to the final particulate form from the InnovaMatrix reference device:

- Sterilization Validation Testing
- Shelf-Life Testing
  - Packaging
  - Product
- Transportation (Packaging Performance) Testing
- Endotoxin
- Physician Usability Testing
- Particle Size Analysis
- Residual Moisture
- Water Absorption
- Chemical Characterization and Toxicity Risk Assessment
- Heavy Metals and Elemental Impurities
- Biocompatibility Testing:
  - Cytotoxicity
  - Intracutaneous Reactivity/Irritation
  - Acute Systemic Toxicity
  - Sensitization
  - Implantation
  - Material-Mediated Pyrogenicity

8. CONCLUSIONS

InnovaMatrix® PD has the same intended use as the predicate device Cook® ECM Powder. The technological characteristics are fundamentally similar to the predicate wound dressing, and chemically the same as the InnovaMatrix® reference device. All devices are porcine-derived, decellularized dressings that are comprised primarily of collagen. The dressings are intended for the management of wounds. Based on the indications for use, technological characteristics, and non-clinical test results, InnovaMatrix™ PD is substantially equivalent to the predicate device Cook® ECM Powder (K152033).