September 29, 2022

Triad Life Sciences, Inc.
Donna Best
Chief Operating Officer
1770 Moriah Woods Blvd, Suite 18
Memphis, Tennessee 38117

Re: K213716
Trade/Device Name: InnovaBurn™
Regulatory Class: Unclassified
Product Code: KGN
Dated: December 16, 2021
Received: December 17, 2021

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,

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)*
K213716

Device Name
InnovaBurn™

Indications for Use *(Describe)*
InnovaBurn™ 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), partial-thickness second degree burns, 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.

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510(k) Summary – K213716

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
Registration Number: 3017660750

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

2. DEVICE

Name of Device: InnovaBurn™
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: Cytal® Wound Matrix 3-Layer (K192725)

4. DEVICE DESCRIPTION

Description

InnovaBurn™ is a decellularized extracellular matrix (ECM) topical wound covering derived from porcine placental tissue. Triad processes the tissue into the ECM topical wound covering. InnovaBurn™ 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 greater than 5 x 5cm ($25cm^2$) up to 20 x 20cm ($400cm^2$).
They are provided as single-use, sterile wound coverings.

5. INDICATION FOR USE

InnovaBurn™ 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), partial-thickness second-degree burns and draining wounds.
The device is intended for one-time use.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

InnovaBurn™ is a decellularized extracellular matrix (ECM) topical wound covering derived from porcine placental tissue. Triad processes the tissue into the ECM topical wound coverings. InnovaBurn™ 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 sizes.

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

Table 1: Device Comparison Table

	Subject Device	**Predicate Device**	**Reference Device**
510(k) Number	K213716	K193552	K192725
Applicant	Triad Life Sciences, Inc.	Triad Life Sciences, Inc.	ACell, Inc.
Device Name	InnovaBurn™	InnovaMatrix®	Cytal® Wound Matrix 3-Layer
Regulation/Class	Unclassified Collagen Wound Dressing	Unclassified Collagen Wound Dressing	Unclassified Collagen Wound Dressing
Product Code	KGN	KGN	KGN
Prescription or OTC?	Prescription	Prescription	Prescription
Indications for Use	InnovaBurn™ 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) partial thickness second-degree burns and draining wounds.	Same, except indications included second-degree burns and not partial thickness second-degree burns.	Same, except indications included second-degree burns and not partial thickness second-degree burns.
Design	Single layer extracellular matrix, Porcine Placenta	Same	Multi-Layer extracellular matrix, Porcine Urinary Bladder Matrix (UBM)

	Subject Device	Predicate Device	Reference Device
Sizes	Greater than 5 x 5 cm (25cm^2) to 20 x 20 cm (400 cm^2)	1 x 1 cm (1 cm^2) to 5 x 5 cm (25cm^2)	16 cm x 25 cm (400 cm^2) & 16 cm x 35 cm (560 cm^2)
Single Use?	Yes	Same	Same
Sterile	E-Beam-sterilized	Same	Same

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

7. PERFORMANCE DATA

The subject device, InnovaBurn™, is comprised of identical materials and is processed and sterilized using identical methods as the predicate device, InnovaMatrix® (K193552).

Biocompatibility testing, including In Vitro Cytotoxicity, Skin Sensitization, Intracutaneous Reactivity, Acute Systemic Toxicity, Subacute Toxicity, Implantation (1-week, 2-week, 4-week, and 13-week), In Vitro Bacterial Reverse Mutation, Mouse Lymphoma Assay, Sub-Chronic Systemic Toxicity, and Material-Mediated Pyrogenicity was conducted on InnovaMatrix® (K193552). All test results were acceptable. Clinical immunogenicity testing, including Human Repeat Insult Patch Testing and Human Skin Prick Testing, was conducted on InnovaMatrix® (K193552). All results were acceptable. Viral inactivation testing was performed on InnovaMatrix® (K193552), and results were acceptable. Compositional testing, including collagen analysis, elastin, hyaluronic acid, laminin, fibronectin, nucleic acid, and sulfated glycosaminoglycan analyses, and cell debris testing was performed on InnovaMatrix® (K193552). All results were acceptable. Heavy metal residual 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)] was conducted on InnovaMatrix® (K193552), and all results were acceptable. Due to the identical nature of the device composition, the biocompatibility testing, clinical immunogenicity testing, viral inactivation testing, compositional testing, and heavy metals residual testing completed on InnovaMatrix® (K193552) were leveraged to support the subject device InnovaBurn™.

The following testing was conducted in support of InnovaBurn™:

- Biological Risk Assessment and Toxicological Evaluation
- Transportation Testing
- Packaging Stability
- Product Stability
- Sterilization Validation Testing
- Endotoxin
- Physician Usability

8. CONCLUSIONS

InnovaBurn™ has the identical indications for use as the predicate device InnovaMatrix®. The technical characteristics are the same as the technological characteristics of the predicate wound dressing. The only modification for the subject device is the addition of larger sizes to the predicate device. The sizes of the subject device are withing the size ranges of the reference device, Cytal® Wound Matrix 3-Layer. The reference device has the same indications for use as the subject device. The predicate, reference, and subject devices are porcine-derived, decellularized dressings that are comprised primarily of collagen and are intended for the management of wounds. Based on the indications for use, technological characteristics, and performance test results, InnovaBurn™ is substantially equivalent to the predicate device InnovaMatrix® (K193552).