July 26, 2024

Convatec Triad Life Sciences, LLC
Victoria Beifuss
Senior Regulatory Affairs Specialist
1770 Moriah Woods Blvd.
Memphis, Tennessee 38117

Re: K241866
Trade/Device Name: InnovaMatrix®FD
Regulatory Class: Unclassified
Product Code: KGN
Dated: June 26, 2024
Received: June 27, 2024

Dear Victoria Beifuss:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Mustafa A. Mazher -S

Yu-chieh Chiu, Ph.D,
Assistant Director
DHT4B: Division of Plastic and
Reconstructive 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K241866

Device Name
InnovaMatrix®FD

Indications for Use *(Describe)*
InnovaMatrix®FD 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.

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510(k) Summary

Date Prepared	26June2024
510(k) Number	K241866
Submitter	Convatec Triad Life Sciences, LLC 1770 Moriah Wood Blvd, Memphis, TN 38117
Contact Person	Rose Beifuss 908-295-7797 Victoria.Beifuss@convatec.com
Name of Device	InnovaMatrix®FD
Common Name	Collagen Wound Dressing
Product Code	KGN
Classification	Unclassified
Primary Predicate Device	InnovaMatrix® AC, cleared via 510(k) K193552
Purpose of Submission	The purpose of this Special 510(k) is to provide a lyophilized version of the previously cleared InnovaMatrix® (rebranded as InnovaMatrix® AC).

DEVICE DESCRIPTION

InnovaMatrix® FD is a lyophilized decellularized extracellular matrix (ECM) topical wound covering derived from porcine placental tissue. InnovaMatrix® FD is composed of collagen, elastin, laminin, fibronectin, hyaluronic acid and sulfated glycosaminoglycans.

The devices are supplied in single layer sheet configurations in size ranges 2 cm x 2 cm, 4 cm x 4 cm, 5 cm x 5 cm. The device is packaged in dual pouch sterile barrier system. The devices are terminally sterilized using electron beam irradiation. The device is intended for one time use.

INDICATIONS FOR USE

InnovaMatrix® FD 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.

PERFORMANCE

The same material used in InnovaMatrix® FD underwent the following biocompatibility, per ISO 10993-1, laboratory and clinical testing on sterilized devices as follows:

Biocompatibility Testing

- 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 System Toxicity
- Material Mediated Pyrogenicity

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
- Heavy metals residuals testing

Clinical Testing

- Human Repeat Insult Patch Testing
- Human Skin Prick Testing

Additional ultimate tensile strength and modulus testing was performed to support shelf-life and stability due to the lyophilized construct of the subject device. Additionally, water absorption testing was performed to ensure the exudate absorption of the subject device remains within specification.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

InnovaMatrix® FD has the same intended use as predicate device, which is for management of wounds. The technological characteristics of InnovaMatrix® FD are similar to the cleared predicate, as both are comprised of animal tissue-derived, collagen extracellular matrix (ECM) scaffolds supplied in a rectangular configurations that are packaged and terminally sterilized. The available sizes of the subject device (2cm x 2cm, 4cm x 4cm, 5cm x5cm) are consistent with the range of sizes of the predicate device (15 mm disk and 4-25cm^2). The subject device and the predicate device both consist of single layer sheets. The difference between the InnovaMatrix® FD and the identified predicate is the dehydration method (lyophilized vs. air dried)

CONCLUSION

Based on testing and comparison to the predicate device, InnovaMatrix® FD is substantially equivalent to the predicate device (K193552).