July 9, 2024

Gel4Med, Inc.
Ana Tellechea
Senior Product Development Manager
1660 Soldiers Field Rd STE 7 #1063
Brighton, Massachusetts 02135

Re: K222025
Trade/Device Name: G4Derm / G4Derm Plus Synthetic Wound Matrix
Regulatory Class: Unclassified
Product Code: FRO

Dear Ana Tellechea:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change for your device cleared on October 11, 2023. Specifically, FDA is updating this SE Letter because FDA inadvertently indicated that the SE determination also included review and clearance of a predetermined change control plan (PCCP). However, your 510(k) submission did not include a PCCP, so FDA is providing this administrative correction. Please see the attached revised clearance letter.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Yu-Chieh Chiu, OHT4: Office of Surgical and Infection Control Devices, Yu-Chieh Chiu, yu-chieh.chiu@fda.hhs.gov.

Sincerely,

Yu-chieh Chiu -S

Yu-Chieh Chiu, Ph.D.
Assistant Director for Wound Devices
DHT4B: Division of Infection Control and Plastic and Reconstructive Surgery
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation & Quality
Center for Devices and Radiological Health

July 9, 2024

Gel4Med, Inc.
Ana Tellechea
Senior Product Development Manager
1660 Soldiers Field Rd STE 7 #1063
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Re: K222025
Trade/Device Name: G4Derm / G4Derm Plus Synthetic Wound Matrix
Regulatory Class: Unclassified
Product Code: FRO
Dated: June 16, 2023
Received: June 16, 2023

Dear Ana Tellechea:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change for your device cleared on October 11, 2023.

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,

Yu-chieh Chiu -S

Yu-Chieh Chiu, Ph.D.
Assistant Director for Wound Devices
DHT4B: Division of Infection Control and Plastic and Reconstructive Surgery
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation & 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)*
K222025

Device Name
G4Derm / G4Derm Plus Synthetic Wound Matrix

Indications for Use *(Describe)*

OTC: May be used for superficial wounds and abrasions and minor burns.

Rx: Under the supervision of health care professionals for the local management of partial- and full-thickness wounds including pressure, and diabetic ulcers; lower extremity ulcers including those of venous, arterial and mixed etiology; surgical wounds; first-degree and partial-thickness burns including management of abrasions and burns associated with dermabrasions and laser resurfacing.

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- K222025
(As required by 21 CFR 807.92)

510(k) Summary

1. Submitter Information

Submitter: Gel4Med, Inc.
1660 Soldiers Field Rd STE 7 #1063
Brighton, MA 02135

Contact: Ana Tellechea, Pharm.D., Ph.D.
Senior Product Development Manager
Email: ana@gelformed.com
Phone: (617) 642-2599

Date Prepared: October 6, 2023

2. Subject Device

Name of Device: G4Derm / G4Derm Plus Synthetic Wound Matrix
Common Name: Wound Dressing
Classification Regulation/Class: Unclassified
Product Code: FRO
Panel: General and Plastic Surgery

3. Predicate and Reference Devices

Predicate Device:

- Woun'Dres® Collagen Hydrogel (Coloplast Corporation); K991202

Reference Devices:

- PuraDERM (3-D Matrix); K193085/K143058
- Excellagen (Tissue Repair Company); K110318

4. Device Description

G4Derm / G4Derm Plus Synthetic Wound Matrix is a sterile, biodegradable hydrogel matrix supplied in a prefilled syringe ready for topical use as primary wound dressing, with or without the use of an optional nozzle. The hydrogel in G4Derm / G4Derm Plus is composed of an aqueous solution of synthetic peptide (≥ 98% sterile water). The device is completely non-animal tissue and non-cellular derived.

G4Derm / G4Derm Plus forms a three-dimensional hydrogel scaffold, which, at a basic structural level, is composed of a matrix of interwoven fibrils formed from individual peptide monomers. This woven network structure, or matrix barrier, is similar to the microarchitecture of endogenous extracellular matrix ("ECM"). This structure also functions as a matrix that holds and donates water to underlying tissue, while providing an effective barrier to cover and protect the wound against the external environment, namely against bacterial penetration.

G4Derm / G4Derm Plus Synthetic Wound Matrix forms a clear, biodegradable hydrogel without expansion in volume. During dressing changes, the unincorporated or unintegrated material may be removed without causing trauma to the underlying tissue by gently flushing / wiping the wound.

5. Intended Use and Indications for Use

OTC: May be used for superficial wounds and abrasions and minor burns.

Rx: Under the supervision of health care professionals for the local management of partial- and full-thickness wounds including pressure, and diabetic ulcers; lower extremity ulcers including those of venous, arterial and mixed etiology; surgical wounds; first-degree and partial-thickness burns including the management of abrasions and burns associated with dermabrasions and laser resurfacing.

6. Comparison With the Predicate Devices

G4Derm / G4Derm Plus is similar in design, function, mechanism of action, physical properties, and presentation to other wound dressings, including collagen-based devices such as Woun'Dres® Collagen Hydrogel (predicate, K991202) and Excellagen (reference device, K110318), as well as synthetic peptide-based hydrogel materials such as PuraDERM (reference device, K193085).

The intended use of G4Derm / G4Derm Plus and its predicate device is the same. They are intended for local wound management, i.e., to protect the wound and provide a moist wound environment conducive to wound healing. The devices are hydrogels that serve as primary contact wound dressings [via direct topical application] for the management of a variety of wounds, including partial and full thickness wounds, and are intended to be used with a secondary wound dressing.

The indications for use for the proposed device are identical to the language from its predicate device. No new indications are proposed.

G4Derm / G4Derm Plus forms a porous hydrogel scaffold that resembles the microarchitecture of endogenous extracellular matrix ("ECM"). G4Derm / G4Derm Plus and its predicate/reference devices form a matrix barrier that fills and conforms to the wound, maintains a moist environment conducive to healing, and covers and protects the wound. The subject device also serves as an antibacterial barrier (based on *in vitro* testing).

G4Derm / G4Derm Plus is composed of a peptide-based aqueous solution, with water being the major component. Woun'Dres is composed of water and collagen, along with skin protectants and a mild preservative, and is also presented as a hydrogel. The minor differences in technological characteristics between G4Derm / G4Derm Plus and its predicates do not present any new questions regarding its safety and effectiveness. The safety and effectiveness of G4Derm / G4Derm Plus is supported by sterility testing, biocompatibility testing, human skin irritation testing, and performance testing including a large animal wound healing model, as well as by additional verification and validation activities.

Table 1: Substantial Equivalence Comparison G4Derm/G4Derm Plus vs Predicate Device

	SUBJECT DEVICE	PREDICATE DEVICE	SUBJECT VS PREDICATE COMPARISON	REFERENCE DEVICE 1	REFERENCE DEVICE 2
Regulatory Information					
Trade Name	G4Derm/G4Derm Plus Synthetic Wound Matrix	Woun'Dres® Collagen Hydrogel Wound Dressing	-	Excellagen	PuraDERM Gel
Applicant	Gel4Med	Coloplast	-	Tissue Repair Company	3D Matrix
510(k) Number(s)	K222025	K991202	-	K110318	K193085; K143058
OTC or Prescription (per 21 CFR801.109)	OTC and Prescription	OTC and Prescription	Same as predicate device.	Prescription	OTC and Prescription
Intended Use	Local management of wounds. Direct topical application to dermal wounds.	Local management of wounds. Direct topical application to dermal wounds.	Same as predicate device.	Local management of wounds. Direct topical application to dermal wounds.	Local management of wounds. Direct topical application to dermal wounds.
Indications for Use	**OTC**: May be used for superficial wounds and abrasions and minor burns. **Rx:** Under the supervision of health care professionals for the local management of partial- and full- thickness wounds including pressure, and diabetic ulcers; lower extremity ulcers including those of venous, arterial, and mixed etiology; surgical wounds; first- degree and partial- thickness burns including management of abrasions and burns associated with dermabrasions and laser resurfacing.	**OTC:** May be used for superficial wounds and abrasions and minor burns. **Rx:** Under the supervision of health care professionals for the local management of partial- and full- thickness wounds including pressure, and diabetic ulcers; lower extremity ulcers including those of venous, arterial, and mixed etiology; surgical wounds; first- and second-degree burns including management of abrasions and burns associated with dermabrasions and laser resurfacing.	Same as predicate device.	**OTC:** N/A **Rx:** Excellagen 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-Moh's surgery, post- laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, second- degree burns, and skin tears) and draining wounds.	**OTC**: PuraDERM is used for the management of minor cuts, minor abrasions, minor wounds, and minor burns (1st degree burns). **Rx:** PuraDERM Gel is indicated for the hydration and management of partial and full-thickness wounds, such as pressure sores, leg ulcers, diabetic ulcers, and surgical wounds, and abrasions and burns associated with dermabrasion and laser resurfacing.

	SUBJECT DEVICE	PREDICATE DEVICE	SUBJECT VS PREDICATE COMPARISON	REFERENCE DEVICE 1	REFERENCE DEVICE 2
Technological Characteristics					
Form	Hydrogel	Hydrogel	Same as predicate device.	Hydrogel	Hydrogel
Single Use	Yes	No	Different but does not affect safety and effectiveness. Reference devices 1 and 2 are included to support technological characteristics.	Yes	Yes
Product Application	Apply directly to the clean wound and fill wound to the level of the surrounding skin.	Apply directly to the clean wound and fill wound to the level of the surrounding skin.	Same as predicate device.	Apply directly to clean wound and fill wound to the level of the surrounding skin.	Apply directly to clean wound and fill wound to the level of the surrounding skin.
Frequency of Application	Change dressing and reapply product as needed.	Change dressing and reapply product as needed. Recommended minimum dressing changes 3 times per week.	Similar to predicate device. Animal performance testing data supports SE. Reference devices 1 and 2 are included to support technological characteristics.	Change dressing as needed and reapply product at once per week intervals.	Change dressing and reapply product as needed. Recommended maximum continuous wear of 7 days.
Labeled Sterile	Yes	No	Different but does not affect safety and effectiveness. Reference devices 1 and 2 are included to support technological characteristics.	Yes	Yes
Presentation	Supplied sterile in single use syringe for direct administration to the wound. Sterile applicator/ nozzle is also provided and may be used if desired.	Supplied non-sterile in multiple use tubes for direct administration to the wound.	Different. Differences were evaluated by biocompatibility and performance testing and support SE. Reference devices 1 and 2 are included to support technological characteristics.	Supplied sterile in single use syringe for direct administration to the wound. Sterile flexible applicator is also provided.	Supplied sterile in single-use syringe for direct administration to the wound. Provided applicator nozzle may be used if desired.
Shelf-Life	12 months (1 year)	2 years	Similar to predicate device.	3 years	3 years

	SUBJECT DEVICE	PREDICATE DEVICE	SUBJECT VS PREDICATE COMPARISON	REFERENCE DEVICE 1	REFERENCE DEVICE 2
Storage	Store at +2℃ to +30℃ (+36℉ to +86℉) Do not freeze. Avoid excessive heat.	Not Specified (room temperature)	Similar to predicate device.	Store at 36°- 46°F / 2 - 8°C. Avoid freezing.	Store in a refrigerator (+2℃ to +8℃ / +35.6℉ to +46.4℉). Do not Freeze.
Safety and Performance Testing					
Biological Evaluation	Performed. Biocompatibility Testing in accordance with ISO 10993-1 demonstrated safety of the device for its intended use [management of wounds]. Clinical (human skin irritation) testing confirmed safety.	Performed. Biocompatibility Testing demonstrated safety of the device for its intended use [management of wounds].	Similar. No new or different questions of safety were raised when compared to the predicate device.	Performed. Biocompatibility Testing in accordance with ISO 10993-1 demonstrated safety of the device for its intended use [management of wounds].	Performed. Biocompatibility Testing in accordance with ISO 10993-1 demonstrated safety of the device for its intended use [management of wounds].
Animal Performance Testing	Performed. GLP pre- clinical performance testing in wound healing animal model demonstrated substantial equivalence regarding safety and effectiveness when compared to the predicate devices.	Unknown	Similar. Animal performance testing demonstrated that the subject device is safe and effective under the proposed conditions of use for its intended use [local management of wounds] and substantial equivalence to its predicate device.	Unknown	Performed. GLP pre-clinical performance testing in wound healing animal model demonstrated substantial equivalence regarding safety and effectiveness when compared to the predicate devices.

7. Safety and Performance Data

G4Derm / G4Derm Plus is terminally sterilized to achieve a minimum sterility assurance level of 10^{-6} in accordance with ISO 17665. G4Derm / G4Derm Plus safety and effectiveness is further supported by pre-clinical data including *in vivo* performance testing in an established porcine wound healing model; biocompatibility testing, as per ISO 10993-1 and consistent with FDA Guidance, Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing"; clinical data (Human Skin Irritation Test); antibacterial barrier effectiveness testing (*in vitro*); additional verification and validation activities.

8. Substantial Equivalence Discussion and Conclusion

G4Derm / G4Derm Plus Synthetic Wound Matrix is substantially equivalent in intended use, indications for use, device design, function, physical properties, principles of operation, instructions for use, biocompatibility, safety, and performance to the predicate device. The technological differences between G4Derm / G4DermPlus and the predicate are minor and do not raise any new or different questions regarding its safety and effectiveness. Any differences in the technological characteristics of the subject device when compared to the predicate have been successfully evaluated using appropriate scientific methods. Safety and performance evaluation including sterility testing, shelf-life testing, biocompatibility testing, clinical testing, animal performance testing, and additional verification and validation activities confirmed that the subject device is as safe, as effective, and performs as well as the predicate device for its intended use and indications for use.

In conclusion, the evaluation of G4Derm / G4Derm Plus Synthetic Wound Matrix has determined it to be substantially equivalent to the previously cleared predicate devices.