December 19, 2025

MedSkin Solutions Dr. Suwelack AG
℅ Justin Gracyalny
Regulatory Affairs Program Manager
Secure BioMed Evaluations
7828 Hickory Flat Hwy Suite 120
Woodstock, Georgia 30188

Re: K250864
Trade/Device Name: MatriDerm pluS+ Bi-Layer
Regulatory Class: Unclassified
Product Code: KGN
Dated: November 21, 2025
Received: November 21, 2025

Dear Justin Gracyalny:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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, PhD
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.

Submission Number *(if known)*

K250864

Device Name

MatriDerm pluS+ Bi-Layer

Indications for Use *(Describe)*

MatriDerm pluS+ is indicated for the management of wounds including full thickness and partial thickness wounds, chronic wounds (e.g. pressure ulcers, venous ulcers, diabetic ulcers, chronic ulcers), surgical wounds (donor sites/grafts, post-Mohs surgery, post-laser surgery, podiatric, wound dehiscence), partial thickness burns, trauma wounds (abrasions, lacerations and skin tears) and draining wounds.

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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510(k) SUMMARY:
MatriDerm pluS+ Bi-Layer (MatriDerm pluS+)

Date Prepared	December 18, 2025
Sponsor	MedSkin Solutions Dr. Suwelack AG Josef-Suwelack-Strasse 2 48727 Billerbeck, Germany
510(k) Contact	Secure BioMed Evaluations Justin Gracyalny, MSE 7828 Hickory Flat Highway, Suite 120 Woodstock, GA 30188 770-837-2681 Regulatory@SecureBME.com
Trade Name	MatriDerm pluS+ Bi-Layer
Common Name	Collagen topical wound dressing
Code – Classification	KGN, Unclassified
Primary Predicate	K201577 MedSkin Solutions Dr. Suwelack AG MatriDerm
Device Description	MatriDerm pluS+ Bi-Layer is a non-pyrogenic, single use, prescription use three-dimensional dermal matrix consisting of two layers. The first layer is composed of collagen fibers, a key component of the native extracellular matrix, and hydrolyzed elastin. The second layer consists of a medical grade silicone grid to control moisture loss from the wound providing a flexible adherent covering for the wound surface and adding increased mechanical strength to the device. The device conforms in the defect space / wound bed and includes a fibrous, porous structure that allows for fluid absorption. The device serves as a scaffold for cellular invasion and capillary growth and promotes a moist environment for the body's natural healing process. The device is supplied sterile and is provided in different sizes providing flexibility of choice based on the treatment protocol, wound location, size, and depth.
Indications for Use Statement	MatriDerm pluS+ is indicated for the management of wounds including full thickness and partial thickness wounds, chronic wounds (e.g. pressure ulcers, venous ulcers, diabetic ulcers, chronic ulcers), surgical wounds (donor sites/grafts, post-Mohs surgery, post-laser surgery, podiatric, wound dehiscence), partial thickness burns, trauma wounds (abrasions, lacerations and skin tears) and draining wounds

Comparison of Technological Characteristics

Characteristic	**Subject Device MedSkin Solutions Dr. Suwelack AG MatriDerm pluS+ Bi-Layer**	**Primary Predicate MedSkin Solutions Dr. Suwelack AG MatriDerm K201577**
Regulation	Unclassified	Unclassified
Product Code	KGN	KGN
Common Name	Collagen-Elastin Wound Dressing	Collagen-Elastin Wound Dressing
Layer Construction	Bilayer	Single layer
Composition of Material	Layer 1: Bovine collagen (collagen types I, III, and V) / bovine elastin Layer 2: Silicon	Bovine collagen (collagen types I, III, and V) / bovine elastin
Collagen Source	Bovine dermis	Bovine dermis
Elastic Source	Bovine ligamentum nuchae	Bovine ligamentum nuchae
Collagen / Elastin Free of Artificial Chemical Crosslinking	Yes	Yes
Primary Function	Provide a moist wound healing environment. Provide a scaffold that allows for wound healing.	Provide a moist wound healing environment. Provide a scaffold that allows for wound healing.
Available Sizes	Range of sizes between 38.48 – 623.7cm²	Range of sizes between 19.24 – 623.7cm²
Resorbable	Yes	Yes
Absorbent	Yes	Yes
Single Use	Yes	Yes
Non-Pyrogenic	Yes	Yes
Sterility	Gamma, 10^{-6} SAL	Gamma, 10^{-6} SAL
Biocompatibility	Biocompatible	Biocompatible

Technological Characteristics

There are no significant technological differences between the subject and predicate device. The subject device uses similar materials (collagen-elastin layer), is of a similar size, has similar design properties, and has the same intended use as the predicate device. Technological differences include that the subject device includes an additional silicon grid layer that is not present in the predicate device. This layer functions to control moisture loss from the wound and adds increased mechanical strength to the device. Non-clinical performance and animal testing supports that the subject device silicon layer does not impede wound healing when compared to the predicate device and does not raise new concerns for safety or effectiveness.

Subject Device Testing Summary

The following non-clinical testing was performed to support substantial equivalence:

- Viral Inactivation (leveraged from K201577)
- Sterilization Validation
- Fluid Absorbency Testing
- Packaging and Matrix Stability Testing
- Bacterial Endotoxin

All testing met the predetermined acceptance criteria (where applicable) and supports substantial equivalence to the predicate device.

MatriDerm pluS+ Bi-Layer was found to be biocompatible for its intended use when tested in compliance with ISO 10993-1. According to this standard and the FDA guidance 'Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" the following aspects were considered for evaluation of biocompatibility for MatriDerm pluS+ Bi-Layer of the category surface device in contact with breached skin for more than 30 days: Cytotoxicity, sensitization, irritation, acute systemic toxicity, material mediated pyrogenicity, implantation (via porcine would healing study), subacute/subchronic systemic toxicity, genotoxicity, chronic toxicity and carcinogenicity.

All testing passed showing the device to be biocompatible for its intended use. The full thickness porcine wound healing study found equivalent wound healing performance for the MatriDerm pluS+ Bi-Layer when compared to the predicate device and untreated control sites.

Conclusions

Based on the similarities of the intended use/indications for use, technological and functional characteristic, and the results of the non-clinical performance testing, the subject device is substantially equivalent to the legally marketed predicate device.