May 14, 2026

Medskin Solutions Dr. Suwelack AG
% Justin Gracyalny
Senior Manager, Regulatory and Technical Compliance
Secure BioMed Evaluations
7828 Hickory Flat Hwy., Suite 120
Woodstock, Georgia 30188

Re: K261224
Trade/Device Name: MatriDerm
Regulatory Class: Unclassified
Product Code: KGN
Dated: April 14, 2026
Received: April 14, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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, 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)*
K261224

Device Name
MatriDerm

Indications for Use *(Describe)*
MatriDerm is indicated for the management of wounds including:
• Partial and full-thickness wounds
• Chronic wounds (e.g. pressure ulcers, venous ulcers, diabetic ulcers)
• Surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence)
• Partial thickness burns
• Trauma wounds (abrasions, lacerations and skin tears)
• Draining wounds

MatriDerm is sterile and for single use only.

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

Date Prepared	May 14, 2026
Sponsor	MedSkin Solutions Dr. Suwelack AG Josef-Suwelack-Strasse 2 48727 Billerbeck, Germany
510(k) Contact	Secure BioMed Evaluations Justin Gracyalny, MSE, RAC 7828 Hickory Flat Highway, Suite 120 Woodstock, GA 30188 770-837-2681 Regulatory@SecureBME.com
Trade Name	MatriDerm
Common Name	Collagen topical wound dressing
Code – Classification	KGN, Unclassified
Primary Predicate	K201577 MedSkin Solutions Dr. Suwelack AG MatriDerm
Reference Device	K250864 MedSkin Solutions Dr. Suwelack AG MatriDerm pluS+ Bi-Layer
Device Description	MatriDerm is a non-pyrogenic, single use, prescription use three-dimensional dermal matrix comprised of bovine collagen fibers and bovine elastin. 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 and configurations providing flexibility of choice based on the treatment protocol, wound location, size, depth and wound bed vascularization.
Indications for Use Statement	MatriDerm is indicated for the management of wounds including: - Partial and full-thickness wounds - Chronic wounds (e.g. pressure ulcers, venous ulcers, diabetic ulcers) - Surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence) - Partial thickness burns - Trauma wounds (abrasions, lacerations and skin tears) - Draining wounds MatriDerm is sterile and for single use only.

Comparison of Technological Characteristics

Characteristic	**Subject Device MedSkin Solutions Dr. Suwelack AG MatriDerm**	**Primary Predicate MedSkin Solutions Dr. Suwelack AG MatriDerm K201577**	**Reference Device MedSkin Solutions Dr. Suwelack AG MatriDerm pluS+ Bi-Layer K250846**
Regulation	Unclassified	Unclassified	Unclassified
Product Code	KGN	KGN	KGN
Common Name	Collagen-Elastin Wound Dressing	Collagen-Elastin Wound Dressing	Collagen-Elastin Wound Dressing
Layer Construction	Single layer	Single layer	Bilayer
Composition of Material	Bovine collagen (collagen types I, III, and V) / bovine elastin	Bovine collagen (collagen types I, III, and V) / bovine elastin	Layer 1: Bovine collagen (collagen types I, III, and V) / bovine elastin Layer 2: Silicone
Collagen Source	Bovine dermis	Bovine dermis	Bovine dermis
Elastic Source	Bovine ligamentum nuchae	Bovine ligamentum nuchae	Bovine ligamentum nuchae
Collagen / Elastin Free of Artificial Chemical Crosslinking	Yes	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.	Provide a moist wound healing environment. Provide a scaffold that allows for wound healing.
Available Size Offerings	Range of sizes between 19.24 –623.7cm^2	Range of sizes between 19.24 –623.7cm^2	Range of sizes between 38.48 –623.7cm^2
Device Thickness	1 – 3mm	1 – 2mm	1 – 3mm
Available Device Offerings	Standard, Flex, and Fenestrated	Standard	Fenestrated
Resorbable	Yes	Yes	Yes
Absorbent	Yes	Yes	Yes
Single Use	Yes	Yes	Yes
Non-Pyrogenic	Yes	Yes	Yes
Sterility	Gamma, 10^{-6} SAL	Gamma, 10^{-6} SAL	Gamma, 10^{-6} SAL
Biocompatibility	Biocompatible	Biocompatible	Biocompatible

Technological Characteristics

The purpose of this submission was to add alternate device configuration offerings (Flex and Fenestrated) and expand the device thickness offerings. There are no significant technological differences between the subject and predicate device. The subject device has an identical material composition, has the same size offerings and similar thickness offerings, has similar design properties, and has the same intended use as the predicate device.

Subject Device Testing Summary

No new safety or performance testing was required to support substantial equivalence for the subject device. The following testing was leveraged from previous submissions:

- Sterilization Validation (leveraged from K201577)
- Endotoxin Testing (leveraged from K201577)
- Biocompatibility Testing (leveraged from K201577, K250864)
- Shelf Life Testing (leveraged from K201577)

Conclusions

Based on the similarities of the intended use/indications for use, technological and functional characteristic, and the leveraged testing from previous submissions, the subject device is substantially equivalent to the legally marketed predicate device.