January 7, 2021

MedSkin Solutions Dr. Suwelack AG
Zuzana Hülsbusch
Senior Regulatory Affairs Specialist
Josef-Suwelack-Strasse 2
Billerbeck, NRW 48727
Germany

Re: K201577
Trade/Device Name: MatriDerm
Regulatory Class: Unclassified
Product Code: KGN
Dated: November 30, 2020
Received: December 4, 2020

Dear Zuzana Hülsbusch:

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,

For Kimberly Ferlin, PhD
Assistant Director (Acting)
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201577

Device Name
MatriDerm

Indications for Use *(Describe)*
MatriDerm 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-Moh's surgery, post-laser surgery, podiatric, wound dehiscence)
- Partial thickness burns
- Trauma wounds (abrasions, lacerations and skin tears)
- 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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

I. Applicant Information

Submitter: MedSkin Solutions Dr. Suwelack AG
Josef-Suwelack-Strasse 2
48727 Billerbeck / Germany

Contact Person: Zuzana Hülsbusch
Senior Regulatory Affairs Specialist
Phone: 0049 | 2543 | 21820
Fax: 0049 | 2543 | 2182-150
E-Mail: zuzana.huelsbusch@medskin-suwelack.com

Establishment Number: 3002636527

Date of preparation: 29 May, 2020

II. Device Information

Trade name: MatriDerm
Common name: Collagen-elastin wound matrix
Classification name: Dressing, Wound, Collagen
Product code: KGN
510(k) Number: K201577
Device class: Unclassified

III. Predicate device

Trade name: PriMatrix Dermal Repair Scaffold
Classification name: Dressing, Wound, Collagen
Product Code: KGN
510(k) Number: K153690
Device Class: Unclassified

IV. Reference device

Trade name:	HYCURE
Classification name:	Dressing, Wound, Collagen
Product Code:	KGN
510(k) Number:	K955506
Device Class:	Unclassified

V. Device description

MatriDerm is a single-use three-dimensional acellular dermal matrix composed of bovine collagen fibers and bovine elastin. The device is supplied sterile and is available in different sizes providing flexibility of choice based on the treatment protocol, wound location, size and depth. The device can be cut to fit the wound.

Indications for Use:

MatriDerm 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-Moh's surgery, post-laser surgery, podiatric, wound dehiscence), partial thickness burns, trauma wounds (abrasions, lacerations and skin tears), draining wounds.

VI. Comparison of Technological Characteristics

MatriDerm is a single-use three-dimensional dermal matrix composed of bovine collagen fibers and bovine elastin. The device is provided in sheet form, supplied sterile and is available in different sizes, indicated for the management of wounds. MatriDerm provides a moist wound healing environment and a scaffold that allows for wound healing. MatriDerm differs from the predicate with respect to the bovine elastin hydrolysate and different source of bovine dermis for collagen.

The table below summarizes the similarities and differences:

	MatriDerm K201577 (Subject device)	**PriMatrix Dermal Repair Scaffold K153690 (Predicate)**
Product Code	KGN	KGN
Indications for Use	Partial and full thickness wounds	Partial and full thickness wounds

	MatriDerm **K201577** **(Subject device)**	**PriMatrix Dermal Repair Scaffold** **K153690** **(Predicate)**
	Chronic wounds (e.g. pressure ulcers, venous ulcers, diabetic ulcers, chronic ulcers) Partial thickness burns Surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence) Trauma wounds (abrasions, lacerations and skin tears) Draining wounds	Pressure, diabetic, and venous ulcers Second-degree burns Surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence) Trauma wounds (abrasions, lacerations, and skin tears) Tunneled/undermined wounds Draining wounds
Rx or OTC	Rx	Rx
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
Intended patient population	Patients with wounds described in the Intended Use statement	Patients with wounds described in the Intended Use statement
Intended Users	Qualified care professionals	Qualified care professionals
Operational environment	Health care environment	Health care environment
Procedure steps	Cleanse the wound Cut dressing to fit Apply dressing Apply suitable secondary coverage	Cleanse the wound Cut dressing to fit Apply dressing Apply suitable secondary coverage
Material	Collagen (≥95,8% (w/w)) (*collagen type I, III, V)* Elastin (≥1.8% (w/w)) Not crosslinked	Collagen Not crosslinked
Collagen Source	Bovine dermis	Fetal bovine dermis
Elastin Source	Bovine ligamentum nuchae	Not added

	MatriDerm K201577 (Subject device)	PriMatrix Dermal Repair Scaffold K153690 (Predicate)
Color	White	White
Sterilization	Terminally sterilized by gamma irradiation	Terminally sterilized by ethylene oxide
Structure	Collagen pad	Collagen pad
Size	3.7cm x 5.2cm x 0.1cm 5.2cm x 7.4cm x 0.1cm 10.5cm x 14.8 cm x 0.1cm 10.5cm x 14.8 cm x 0.2cm 21.0cm x 29.7cm x 0.1cm 21.0cm x 29.7cm x 0.2cm	8cm x 8cm 8cm x 8cm Fenestrated 8cm x 8cm Meshed 8cm x 12cm 8cm x 12cm Meshed 10cm x 12cm 10cm x 25cm 10cm x 25cm Meshed 20cm x 25cm
Adaptable	Yes, can be trimmed in dry or wet state to meet the individual patient's needs	Yes, can be trimmed in dry or wet state to meet the individual patient's needs
Shelf-life	60 months	60 months
Biocompatible	Yes, ISO 10993-1	Yes, ISO 10993-1
Biodegradable	Yes	Yes
Non-pyrogenic	Yes	Yes
Absorbency	22.8 g/g 11.77 g/100cm²	3.45 g/g 7.82 g/100cm²
Time to full absorbency	21 seconds	16 seconds
Virus Inactivation	Compliant with ISO 22442 and FDA Guidance on Medical Device Containing Materials from Derived Animal Sources (Except for In Vitro Diagnostics	performed

Overall, the differences in technological characteristics of the subject and predicate device do not raise any different questions of safety and effectiveness.

VII. Performance Test Data

Biocompatibility

MatriDerm was determined to be biocompatible based on ISO 10993-1 and "FDA General Guidance on Biological Evaluation of Medical Devices- Part 1: Evaluation and testing within a risk management process." Based on the intended use of MatriDerm, the device is classified according to ISO 10993-1 as a surface device with permanent (>30 days) contact with breached, compromised surfaces. Following biological endpoints were considered for the evaluation of the biological safety of MatriDerm: physical and chemical characterization, cytotoxicity, sensitization, irritation or intracutaneous reactivity, acute systemic toxicity, subchronic and subacute toxicity, genotoxicity, implantation, chronic toxicity, carcinogenicity, material-mediated pyrogenicity. The recommended tests were successfully performed/evaluated on final, finished and sterile subject device and the device is considered to be biocompatible.

Bench

- Fluid absorbency
- Sterilization Validation
- Bacterial Endotoxin
- Viral Inactivation
- Device Characterization

Clinical

Human Repeat Insult Patch Testing (HRIPT) and Skin Prick Testing (SPT) were performed to demonstrate MatriDerm is non irritating and non-immunogenic. In 60 subjects, the HRIPT demonstrated MatriDerm was not irritating or immunogenic for a type 4/delayed type hypersensitivity. In the Skin Prick Testing, 1 out of the 22 subjects had a positive wheal response at the 15 minute time point in the positive control site, negative control site, and the product test site. The product test site wheal was bigger than the negative control and about the same size as the positive control. At the 6 hour and 1-2 day time points, all sites were negative. The Skin Prick Testing demonstrated MatriDerm has a low immunogenic potential.

VIII. Conclusion on substantial equivalence

The technological characteristics of the proposed device are similar to the predicate. Performance of the device is not impacted by the different source of bovine dermis for collagen and addition of hydrolyzed elastin. The conclusions drawn from the data included in this submission demonstrate that MatriDerm is as safe, as effective and is substantially equivalent to the predicate device in indication for use, mechanism of action, performance, animal derived collagen, and biocompatibility.