May 5, 2022

Geistlich Pharma AG
% Stephen Rhodes
Principal
Streamline Regulatory
3502 Dundee Dr
Chevy Chase, Maryland 20815

Re: K213607
Trade/Device Name: Geistlich Wound Matrix PLUS
Regulatory Class: Unclassified
Product Code: KGN

Dear Stephen Rhodes:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated April 28, 2022. Specifically, FDA is updating this SE Letter to correct the indications for use due to an administrative error.

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

Sincerely,

Julie A. Morabito -S

Julie Morabito, Ph.D.
Assistant Director
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

April 28, 2022

Geistlich Pharma AG
% Stephen Rhodes
Principal
Streamline Regulatory
3502 Dundee Dr
Chevy Chase, Maryland 20815

Re: K213607
Trade/Device Name: Geistlich Wound Matrix PLUS
Regulatory Class: Unclassified
Product Code: KGN
Dated: December 17, 2021
Received: December 20, 2021

Dear Stephen Rhodes:

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,

Julie A. Morabito -S

Julie Morabito, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
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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)*
K213607

Device Name

Wound Matrix PLUS

Indications for Use *(Describe)*

Wound Matrix PLUS is intended for the management of wounds including:

- Partial and full-thickness wounds
- Pressure ulcers
- Venous ulcers
- Diabetic ulcers
- Chronic vascular ulcers
- Surgical wounds (donor sites/grafts, post-Mohs surgery, post-laser surgery, podiatric, wound dehiscence)
- Trauma wounds (abrasions, lacerations,second-degree burns, and skin tears)
- Draining wounds
- Tunneled/undermined 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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Department of Health and Human Services
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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."

In accordance with 21 CFR 807.87(h) and 21 CFR 807.92, the 510(k) Summary for Wound Matrix PLUS is provided below.

1. SUBMITTER

Geistlich Pharma AG
Bahnhofstrasse 40
CH-6110 Wolhusen
Switzerland

Contact Person: Erik Wirth
Phone: +41 41 492 69 28
Email: Erik.Wirth@geistlich.ch

Prepared By: Stephen P. Rhodes, Streamline Regulatory
stephen.rhodes@streamlineregulatory.com
Date Prepared: April 12, 2022

2. DEVICE

Name of Device: Wound Matrix PLUS
Common Name: Collagen Wound Dressing
Classification Regulation: Unclassified
Regulatory Class: Unclassified
Product Code: KGN
Panel: General and Plastic Surgery

3. PREDICATE DEVICE

Predicate Device: ACell Inc.'s Cytal Wound Matrix (K152721)

Reference Device: Geistlich Fibro-Gide (K171050)

4. DEVICE DESCRIPTION

Geistlich Wound Matrix PLUS is an animal-sourced, acellular extracellular matrix (ECM) wound dressing that is derived from porcine tissue. The porcine tissue undergoes processing to remove proteins and inactivate viruses. The device is intended for use in the management of wounds. Wound Matrix PLUS is terminally sterilized using gamma irradiation in its packaging.

The device is offered in various sizes and can be shaped to the required dimension using standard sterile instruments (scissors or scalpel).

The device is intended to be used by licensed healthcare practitioners and will be supplied sterile for single one-time use.

5. INDICATIONS FOR USE

Wound Matrix PLUS is intended for the management of wounds including:

- Partial and full-thickness wounds
- Pressure ulcers
- Venous ulcers
- Diabetic ulcers
- Chronic vascular ulcers
- Surgical wounds (donor sites/grafts, post-Mohs surgery, post-laser surgery, podiatric, wound dehiscence)
- Trauma wounds (abrasions, lacerations, superficial second-degree burns, and skin tears)
- Draining wounds
- Tunneled/undermined wounds

The device is intended for one-time use.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The similarities and differences in technological characteristics between the subject device (Wound Matrix PLUS), predicate device (Cytal Wound Matrix – K152721), and the reference device (Geistlich Fibro-Gide - K171050) are summarized below.

Wound Matrix PLUS and Cytal Wound Matrix (K152721) are both porcine-derived matrices intended for wound management. The wound dressings provide a moist environment that is conducive to wound healing.

The subject device is offered in one thickness (6mm) and the following sizes: 10 x 10 mm, 10 x 20 mm, 10 x 40 mm, 10 x 80 mm, 15 x 15 mm, 15 x 20 mm, 20 x 20 mm, 20 x 40 mm, and 25 x 25 mm. The predicate's largest size is 100 x 150 mm and is provided in a range of thicknesses (one to eight layers) up to 3-4 mm. The difference in size and number of layers between Wound Matrix PLUS and Cytal Wound Matrix does not raise different questions of safety or effectiveness in the subject device. Both the subject and predicate device can be shaped to the desired dimensions or multiple devices can be used. Additionally, the predicate device is sterilized with electron beam irradiation and the subject device is gamma-sterilized. Both devices are provided sterile with an SAL of 10^{-6}.

Technological Characteristics

	Wound Matrix PLUS K213607	**Cytal Wound Matrix K152721**
Material Origin	Porcine derived collagen	Porcine derived collagen
Sizes/ Form	10 x 10 mm, 10 x 20 mm, 10 x 40 mm, 10 x 80 mm, 15 x 15 mm, 15 x 20 mm, 20 x 20 mm, 25 x 25 mm, 20 x 40 mm	Up to 100 x 150 mm
Thickness	6 mm	3 – 4 mm
Sterilization	Irradiation (gamma)	Irradiation (electron beam)
Sterility Level	SAL of 10^{-6}	SAL of 10^{-6}

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

Lastly, the subject Wound Matrix PLUS has the same technological characteristics as the cleared Geistlich Fibro-Gide reference device (K171050) although with different indications.

7. PERFORMANCE DATA

For all performance testing, the testing was leveraged from the previously reviewed and cleared reference device (Geistlich Fibro-Gide (K171050) that is identical in composition and technology to the subject device. The substantial equivalence evaluation of Wound Matrix PLUS and Cytal Wound Matrix was supported by non-clinical performance including GLP 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" and laboratory testing.

Wound Matrix PLUS is classified as a permanent contact device. Biocompatibility information is summarized in the table below:

Leachables and Biocompatibility Test Results

Test (Standard)	Test method	Results
Cytotoxicity (ISO 10993-5)	In vitro mouse L929 fibroblast cell culture assay	Non-cytotoxic
Irritation (ISO 10993-10)	Intracutaneous reactivity in the rabbit	Not irritant
Sensitization (ISO 10993-10)	Guinea pig maximization test	Not sensitizing
Acute systemic toxicity (ISO 10993-11)	Acute systemic toxicity test in the mouse	No acute systemic toxicity
Pyrogenicity (USP <151>)	Rabbit pyrogen test	Non-pyrogenic
Genotoxicity (ISO 10993-3)	Bacterial reverse mutagenicity assay in *Salmonella typhimurium* and *Escherichia coli* (Ames test)	Non-mutagenic
	In vitro chromosomal aberration study in human lymphocytes	Not genotoxic
	Mouse peripheral blood micronucleus study	Not genotoxic
Local tissue response after implantation (ISO 10993-6)	4-week, 12-week and 26 week subcutaneous implantation in rats	Local tissue effects: slight irritant. Systemic toxicity: No evidence of systemic toxicity
Subchronic systemic toxicity (ISO 10993-11)	4-week subcutaneous implantation in rats, with systemic toxicity endpoint	No subchronic toxicity
Chronic systemic toxicity (ISO 10993-11)	26-week subcutaneous implantation in rats, with systemic toxicity endpoint	No chronic toxicity
Chemical Characterization Extractable Substances (ISO 10993-18)	GC/Headspace and ICP	No product-related semi-volatile organic compounds were detected in the GC/MS fingerprint chromatograms of the test material

The results indicate that Wound Matrix PLUS is biocompatible.

Per FDA guidance on shelf life, sterilization, and devices containing animal-derived material, the following laboratory studies were also conducted:

Laboratory Testing

- Viral Inactivation: Viral validation studies per ISO 22442-3 Medical devices utilizing animal tissues and their derivatives – Part 3: Validation of the elimination and/or inactivation of viruses and transmissible spongiform encephalopathy (TSE) agents and requirements of ICH Q5A Quality of biotechnological products: viral safety evaluation of biotechnology products derived from cell lines of human or animal origin.
- Expiration Dating / Shelf Life for Three Year Shelf Life. Packaging stability was confirmed by ISO 11607 Packaging for terminally sterilized medical devices, and real-time shelf life testing was conducted on device properties

The results support the viral safety of the device and the product shelf life of three years.

8. CONCLUSIONS

The subject Wound Matrix PLUS has the same intended use and indications as the predicate Cytal Wound Matrix (K152721).

There are similar technological characteristics between the subject Wound Matrix PLUS and the predicate Cytal Wound Matrix. The differences in technological characteristics do not raise any different questions of safety or effectiveness.

Wound Matrix PLUS has the same design, material, manufacturing, packaging and sterilization to the reference device, Fibro-Gide (K171050).