March 19, 2026

Geistlich Pharma AG
% Roshana Ahmed
Principal Consultant
Quaras, LLC
2101 Camino Rey
Fullerton, California 92833

Re: K260532
Trade/Device Name: Derma-Gide
Regulatory Class: Unclassified
Product Code: KGN
Dated: February 17, 2026
Received: February 17, 2026

Dear Roshana Ahmed:

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 13485 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 Medical Device File (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,

MUSTAFA A. MAZHER -S

*For* 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)*
K260532

Device Name
Derma-Gide

Indications for Use *(Describe)*
Derma-Gide 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 Moh's surgery, post laser surgery, podiatric, wound dehiscence)
• trauma skin wounds (abrasions, laceration, partial thickness second degree burns, skin tears)

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:

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# 510(k) Summary (as required by 21 CFR 807)

## I. Submitter

Geistlich Pharma AG
Bahnhofstrasse 40
CH-6110 Wolhusen
Switzerland
Phone: +41 41 492 53 39

Contact Person: Erik Wirth, Team Lead Regulatory Services
Date Prepared: March 19, 2026

## II. Device

| | |
|---|---|
| Device Proprietary Name: | Derma-Gide |
| Common or Usual Name: | Collagen Wound Dressing |
| Classification Name: | Wound dressing with animal-derived material(s) |
| Product Code: | KGN |
| Device Classification | Unclassified |

## III. Predicate Device

Substantial equivalence is claimed to the following devices:

| Product Name | 510(k) | Applicant |
|---|---|---|
| Geistlich Derma-Gide™ | K182838 | Geistlich Pharma AG |
| Geistlich Wound Matrix | K171842 | Geistlich Pharma AG |

## IV. Device Description

Derma-Gide is a sterile, single-use only, acellular advanced wound care device primarily derived from porcine collagen. Derma-Gide features a bilayer structure. The upper dense compact collagen layer protects the wound. This structure has a smooth texture with appropriate pull-out strength properties to allow suturing. The second lower layer consists of a thick, porous spongeous collagen scaffold.

Derma-Gide is provided in rectangular and round shapes in multiple sizes/diameters.

## V. Indications for Use

Derma-Gide 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 Moh's surgery, post laser surgery, podiatric, wound dehiscence)
- trauma skin wounds (abrasions, laceration, partial thickness second degree burns, skin tears)

## VI. Comparison of Technological Characteristics

The indications for use statements for the subject and predicate devices are identical.

The subject Derma-Gide has the same technological characteristics as the predicate Geistlich Wound Matrix (K182838 and K171842). There are no changes to the materials of construction, material characteristics, or sterilization methods compared to the Derma-Gide variants cleared under K171842 and K182838. The only difference is the addition of a 5 x 6 cm rectangular variant which is packaged in a different secondary sterile barrier pouch. Fixation by sutures is possible for all sizes and all of the devices can be trimmed as needed. The additional size is provided for user convenience.

A comparison of the subject and predicate devices is provided below.

| | **Derma-Gide (Subject Device)** | **Geistlich Derma-Gide (K171842 and K182838)** | **Analysis** |
|---|---|---|---|
| **Manufacturer** | Geistlich Pharma AG | Geistlich Pharma AG | Identical |
| **Animal Material** | Porcine collagen | Porcine collagen | Identical |
| **Composition** | Collagen Type 1: ~68%<br>Collagen Type 2: ~15%<br>Elastin: ~14% | Collagen Type 1: ~68%<br>Collagen Type 2: ~15%<br>Elastin: ~14% | Identical |
| **Thickness** | 2.5 - 5 mm | 2.5 - 5 mm | Identical |
| **Shape** | Rectangle<br>Round | Rectangle<br>Round | Identical |
| **Sizes** | Rectangular:<br>5 cm x 6 cm | Rectangular:<br>1.0 x 1.5 cm<br>1.5 x 2.0 cm<br>2.0 x 2.0 cm<br>2.0 x 3.0 cm<br>2.0 x 4.0 cm<br>3.0 x 4.0 cm | Equivalent |

| | Derma-Gide (Subject Device) | Geistlich Derma-Gide (K171842 and K182838) | Analysis |
|---|---|---|---|
| | | Round: 10, 12, 14, 16, 18, 20, 22, and 24 mm diameters | |
| **Single-Use** | Yes | Yes | Identical |
| **Sterilization** | Gamma | Gamma | Identical |

The purpose of this submission is to introduce a 5 x 6 cm rectangular variant to the product line and to notify the Agency of non-significant changes to manufacturing facilities and equipment, sources of animal materials, and release testing methods. These changes do not raise different questions of safety and effectiveness when compared to the predicate device and the testing to support the minor technological differences are discussed in the Performance Data section below.

## VII. Performance Data

Results from biocompatibility, sterilization, shelf-life, packaging validation and clinical performance studies from the applicant's own predicate device (K171842 and K182838) were leveraged in support of substantial equivalence.

Bench testing was performed to support that the new larger variant meets the same product specifications and acceptance criteria as the predicate device, including DSC and Porosity.

## VIII. Conclusion

The information provided above supports that the subject Derma-Gide is comparable to the predicate devices with respect to intended use and technological characteristics. Therefore, it is concluded that Derma-Gide is substantially equivalent to the identified predicate devices.