November 8, 2018

Geistlich Pharma AG
% Samie Allen
Consultant, Devices
Biologics Consulting Group, Inc.
1555 King Street, Suite 300
Alexandria, Virginia 22314

Re: K182838
Trade/Device Name: Geistlich Derma-Gide
Regulatory Class: Unclassified
Product Code: KGN
Dated: October 5, 2018
Received: October 9, 2018

Dear Samie Allen:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Cynthia Chang -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K182838

Device Name
Geistlich Derma-Gide™

Indications for Use *(Describe)*
The Geistlich 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, 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.

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

1. SUBMITTER

Geistlich Pharma AG
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Prepared By: Samie Allen, Biologics Consulting Group, sallen@biologicsconsulting.com
Date Prepared: November 7, 2018

2. DEVICE

Name of Device: Geistlich Derma-Gide™
Common Name: Collagen Wound Dressing
Classification Regulation/Class: unclassified
Product Code: KGN
Panel: General and Plastic Surgery

3. PREDICATE DEVICE

Predicate Device: Geistlich Wound Matrix (subsequently renamed to Geistlich Derma-Gide™) (K171842)

4. DEVICE DESCRIPTION

Geistlich Derma-Gide™ is an acellular advanced wound care device. The Geistlich Derma-Gide™ is derived from porcine tissue (mostly collagen Type 1) and is processed using proprietary technologies to remove bacteria and inactivate viruses. Geistlich Derma-Gide™ features a bilayer structure. The upper dense compact collagen layer protects the wound and the open healing process. 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.

The sizes cleared under K171842 include:

- Rectangular: 1.5 x 2.0 cm; 2.0 x 3.0 cm; and 3.0 x 4.0 cm; the thickness ranges from 2.5-5 mm

The new sizes in this Special 510(k) include:

- Rectangular: 1.0 x 1.5 cm; 2.0 x 2.0 cm; 2.0 x 4.0 cm; the thickness ranges from 2.5-5 mm
- Round (disk) shape: 10, 12, 14, 16, 18, 20, 22, and 24 mm diameters; the thickness ranges from 2.5-5 mm.

Fixation by sutures is possible. The device can be trimmed as needed. The device is terminally sterilized (by gamma irradiation) in its packaging. The device is intended to be used by licensed surgeons and will be supplied sterile for single use.

5. INDICATION FOR USE

The Geistlich 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, second degree burns, skin tears)

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The subject Geistlich Derma-Gide™ has the same technological characteristics as the predicate Geistlich Wound Matrix (K171842). They have the same thickness (2.5-5 mm), source material, manufacturing, sterilization, and packaging. The only difference is that 3 additional rectangular sizes and 8 round (disk) sizes are being added to the sizes cleared under K171842. Fixation by sutures is possible for all sizes. All devices can be trimmed as needed.

All of the new sizes are smaller than the 3.0 x 4.0 cm device size cleared under K171842. However, the new range of sizes or the additional round-shaped sizes do not raise any new questions of safety or effectiveness based on the intended use of the devices. The additional sizes and shapes are for user convenience and minimizing waste.

Table 1 provides a summary comparison between the subject and predicate devices.

Table 1: Device Comparison Table

	Subject Device	**Predicate Device**
510(k) Number	TBD	K171842
Applicant	Geistlich Pharma AG	Geistlich Pharma AG
Device Name	Geistlich Derma-Gide	Geistlich Wound Matrix (tradename subsequently changed to Geistlich Derma-Gide)
Classification Regulation, Class	Unclassified	same
Product Code	KGN	same
Indications for Use	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, second degree burns, skin tears)	same
Device Description	The Geistlich Derma-Gide is derived from porcine tissue (mostly collagen Type 1) and is processed using proprietary technologies to remove bacteria and inactivate viruses. Geistlich Derma-Gide features a bilayer structure. The upper dense compact layer protects the wound and the open healing process. 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 scaffold.	same
Material	Porcine	same
Thickness	2.5 - 5 mm	same
Range of sizes	New Sizes: Rectangular: 1.0 x 1.5 cm; 2.0 x 2.0 cm; 2.0 x 4.0 cm Round (disk) shape: 10, 12, 14, 16, 18, 20, 22, and 24 mm diameters	Rectangular: 1.5 x 2.0 cm; 2.0 x 3.0 cm; and 3.0 x 4.0 cm
Single Use	Yes	same

	Subject Device	**Predicate Device**
Sterile	Gamma-sterilized	same

7. PERFORMANCE DATA

Because there is no change to the device thickness, source material, manufacturing, sterilization, or packaging compared to the predicate K171842, the existing biocompatibility, sterilization, and shelf life information from K171842 fully applies.

New performance testing was not necessary to support the additional sizes/shapes or the updates to the IFU.

8. CONCLUSIONS

The subject Geistlich Derma-Gide™ is identical in indications to the predicate K171842. The design changes involve 3 additional rectangular sizes and 8 new round (disk) shaped versions of the device. The additional design configurations are intended to simply provide ready-to-use shapes which require less trimming to the wound size to reduce waste. Overall, the convenience for the user is improved. The new design configurations raise no new questions of safety or effectiveness.

There are no changes in product thickness, source material, manufacturing, sterilization, or packaging.

None of the changes to the IFU raise a new question of safety and effectiveness.

Accordingly, the Geistlich Derma-Gide™ is substantially equivalent to the predicate Geistlich Wound Matrix cleared under K171842.