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

November 25, 2025

Re: K252253
Trade/Device Name: Geistlich Mucograft® /Geistlich Mucograft® Seal; Geistlich Fibro-Gide®
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: Class II
Product Code: NPL
Dated: October 20, 2025
Received: October 27, 2025

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 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 systems (QS) regulation (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,

Sherrill Lathrop Blitzer

for Andrew Steen
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental 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)*
K252253

Device Name
Geistlich Mucograft® /Geistlich Mucograft® Seal;
Geistlich Fibro-Gide®

Indications for Use *(Describe)*
Geistlich Mucograft® and Geistlich Mucograft® Seal are indicated for:

- covering of implants placed in immediate or delayed extraction sockets;
- localized gingival augmentation to increase keratinized tissue (KT) around teeth and implants;
- alveolar ridge reconstruction for prosthetic treatment; and
- recession defects for root coverage.

Geistlich Fibro-Gide® is intended for soft tissue augmentation. It is indicated for:

- Localized gingival augmentation to increase keratinized tissue (KT) around teeth and implants
- Alveolar ridge reconstruction for prosthetic treatment
- Recession defects for root coverage

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) Summaries

Geistlich Mucograft® and Geistlich Mucograft® Seal

I. Submitter

Geistlich Pharma AG
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CH-6110 Wolhusen
Switzerland
Phone: +41 41 492 55 55

Contact Person: Marco Steiner, Head Regulatory Affairs Management
Date Prepared: November 24, 2025

II. Device

Device Proprietary Name:	Geistlich Mucograft® Geistlich Mucograft® Seal
Common or Usual Name:	Collagen Matrix
Classification Name:	Barrier, Animal Source, Intraoral
Regulation Number:	872.3930
Product Code:	NPL
Device Classification	II

III. Predicate Device

Substantial equivalence is claimed to the following devices:

Product Name	**510(k)**	**Applicant**
Geistlich Mucograft® and Mucograft® Seal	K210280	Geistlich Pharma AG

The following devices are referenced within the submission:

- Mucograft, K102531, Ed. Geistlich Soehne AG Fuer Chemische Industrie
- Mucograft Collagen Matrix, K073711, Ed. Geistlich Soehne AG Fuer Chemische Industrie

IV. Device Description

Geistlich Mucograft® and Geistlich Mucograft® Seal are surgically implanted, fully resorbable devices intended for oral tissue regeneration. The matrices are made of collagen without further cross-linking. All configurations of the product are sterilized in a double package by gamma irradiation. Geistlich Mucograft® and Geistlich Mucograft® Seal are composed of two structures: one smooth structure and one porous structure. The device allows tissue adherence as a prerequisite for favorable wound healing. The "outer" side (i.e., turned towards the soft tissue) with a smooth surface consists of compact collagen and has a smooth texture with the appropriate elastic properties to accommodate suturing. The "inner" porous structure consists of collagen fibers in a loose, porous arrangement to allow cell invasion for soft tissue ingrowth. This roughened surface is placed next to the host tissue to facilitate tissue integration.

The products are provided as follows:

- Geistlich Mucograft®: 15 x 20 mm, 20 x 30 mm, and 30 x 40 mm
- Geistlich Mucograft® Seal: 8 mm and 12 mm diameter

V. Indications for Use

Geistlich Mucograft® and Geistlich Mucograft® Seal are indicated for:

- covering of implants placed in immediate or delayed extraction sockets;
- localized gingival augmentation to increase keratinized tissue (KT) around teeth and implants;
- alveolar ridge reconstruction for prosthetic treatment; and
- recession defects for root coverage.

VI. Comparison of Technological Characteristics

The Indications for Use Statement is identical to the predicate device.

The subject device is identical to the predicate device with respect to materials characteristics, manufacturing and sterilization methods, packaging, and size. Both the subject and predicate devices have identical final product specifications. A comparison of the subject and predicate device is provided in the table below.

	Subject Device	Geistlich Mucograft® and Mucograft® Seal (K210280, K192042)
Material	Porcine collagen	Same
Shape	Geistlich Mucograft®: Rectangle Geistlich Mucograft® Seal: Cirle	Same
Sizes	Geistlich Mucograft®: 15 x 20 mm 20 x 30 mm 30 x 40 mm Geistlich Mucograft® Seal: 8 mm diameter 12 mm diameter	Same
Single-Use	Yes	Same
Sterilization	Gamma	Same

The purpose of this submission is to obtain clearance for the use of an alternate supplier of porcine raw material. This change does not raise different questions of safety and effectiveness and the slight technological differences are addressed by the information described in the Performance Data section below.

VII. Performance Data

Mechanical testing, biocompatibility (K073711), sterilization (K102531), shelf-life (K102531), and clinical performance testing (K102531) from the applicant's own predicate device was leveraged in support of substantial equivalence.

The following non-clinical data was provided within this submission to demonstrate substantial equivalence:

- results from a viral inactivation study performed in accordance with ISO 22442-3
- results from real-time stability studies performed in accordance with ICH Q1A (R) (extension of studies submitted in support of K171050)

VIII. Conclusion

The subject devices are identical to the predicate device. The addition of a new raw material supplier does not raise different questions of substantial equivalence. Therefore, it is concluded that Geistlich Mucograft® and Geistlich Mucograft® Seal are substantially equivalent to the identified predicate device.

Geistlich Fibro-Gide®

I. Submitter

Geistlich Pharma AG
Bahnhofstrasse 40
CH-6110 Wolhusen
Switzerland
Phone: +41 41 492 55 55

Contact Person: Marco Steiner, Head Regulatory Affairs Management
Date Prepared: November 24, 2025

II. Device

Device Proprietary Name:	Geistlich Fibro-Gide®
Common or Usual Name:	Bone Grafting Material
Classification Name:	Barrier, Animal Source, Intraoral
Regulation Number:	872.3930
Product Code:	NPL
Device Classification	II

III. Predicate Device

Substantial equivalence is claimed to the following device:

Product Name	**510(k)**	**Applicant**
Geistlich Fibro-Gide®	K171050	Geistlich Pharma AG

IV. Device Description

Geistlich Fibro-Gide® is a fully resorbable, porous, collagen matrix of porcine origin of a spongious consistency. The collagen is extracted from veterinary certified pigs and is carefully purified to avoid antigenic reactions. The collagen scaffold is weakly crosslinked. Geistlich Fibro-Gide® is sterilized in double packaging by Gamma-irradiation.

Geistlich Fibro-Gide® is an implantable device intended for use in soft tissue augmentation procedures. As described in more detail below, the device is indicated specifically for insufficient tissue volume at the alveolar ridge and for soft tissue recession. It has mechanical properties appropriate to withstand the mechanical stresses that occur after wound closure in soft tissue augmentation procedures, i.e., it has good volume stability and it withstands early

resorption to allow the formation of new soft tissue and degrades over time. In addition, the matrix is designed with an appropriate thickness to provide sufficient space for the ingrowth of new soft tissue. Due to its good wettability, suturability and biological properties, the device becomes well integrated into the surrounding soft tissue.

The products are provided as follows:

- 15 x 20 x 6 mm
- 20 x 40 x 6 mm
- 15 x 20 x 3 mm
- 20 x 40 x 3 mm

V. Indications for Use

Geistlich Fibro-Gide® is intended for soft tissue augmentation. It is indicated for:

- Localized gingival augmentation to increase keratinized tissue (KT) around teeth and implants
- Alveolar ridge reconstruction for prosthetic treatment
- Recession defects for root coverage

VI. Comparison of Technological Characteristics

The Indications for Use Statement is identical to the predicate device.

The subject device is identical to the predicate device with respect to materials characteristics, manufacturing and sterilization methods, and packaging. Both the subject and predicate device have identical final product specifications. A comparison of the subject and predicate device is provided in the table below.

	Subject Device	**Geistlich Fibro-Gide® (K171050)**
Material	Porcine collagen	Same
Shape	Rectangle	Same
Sizes	15 x 20 x 6 mm 20 x 40 x 6 mm 15 x 20 x 3 mm 20 x 40 x 3 mm	Different
Single-Use	Yes	Same
Sterilization	Gamma	Same

The purpose of this submission is to obtain clearance for the use of an alternate supplier of porcine raw material and notify the FDA of the introduction of the additional 3 mm size variants,

slight modifications to the device labels and instructions for use, changes to the manufacturing process, and extension to shelf life. These changes do not raise different questions of safety and effectiveness and are addressed by the information summarized within the Performance Data section below.

VII. Performance Data

Mechanical testing, biocompatibility (K171050), sterilization (K171050), shelf-life (K171050), and non-clinical and clinical performance testing (K171050) from the applicant's own predicate device was leveraged in support of substantial equivalence.

The following non-clinical data was provided within this submission to demonstrate substantial equivalence:

- results from a suturability study on the 3 mm variants according to methods used in K171050
- results from a viral inactivation study performed in accordance with ISO 22442-3
- results from real-time stability studies performed in accordance with ICH Q1A (R) (extension of studies submitted in support of K171050)

VIII. Conclusion

The subject device is identical to the predicate device. The addition of a raw material supplier does not raise different questions of substantial equivalence. Therefore, it is concluded that Geistlich Fibro-Gide® is substantially equivalent to the identified predicate device.