Geistlich Pharma AG
% Roshana Ahmed
Sr Regulatory Specialist
TELOS Partners LLC
571 Christina Lake Drive
Lakeland, Florida 33813

March 03, 2021

Re: K210280
Trade/Device Name: Geistlich Mucograft®, Geistlich Mucograft® Seal
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: Class II
Product Code: NPL
Dated: January 30, 2021
Received: February 1, 2021

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 (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 Andrew Steen
Assistant Director
DHT1B: Division of Dental 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K210280

Device Name
Geistlich Mucograft® and Geistlich Mucograft® Seal

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.

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.

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510(k) Summary

I. Submitter

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

Contact Person: Marco Steiner, Deputy Director Regulatory Affairs
Date Prepared: March 3, 2021

II. Device

Device Proprietary Names:	Geistlich Mucograft® Geistlich Mucograft® Seal
Common or Usual Name:	Collagen Matrix
Classification Name:	Bone Grafting Material
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	K192042	Geistlich Pharma AG
	K140518	Geistlich Pharma AG
	K102531	Geistlich Pharma AG
	K073711	Geistlich Pharma AG

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 devices are equivalent to the predicate devices with respect to materials characteristics, manufacturing and sterilization methods, and packaging. 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 Devices	**Predicate Devices (K192042, K140518, K102531, K073711)**	**Analysis**
Material	Porcine collagen	Same	Equivalent
Shape	Geistlich Mucograft®: Rectangle Geistlich Mucograft® Seal: Circle	Same	Equivalent
Sizes	Geistlich Mucograft®: 15 x 20 mm 20 x 30 mm 30 x 40 mm Geistlich Mucograft® Seal: 8 mm diameter 12 mm diameter	Geistlich Mucograft®: 15 x 20 mm 20 x 30 mm 30 x 40 mm Geistlich Mucograft® Seal: 8 mm diameter	Different. The subject devices include a larger size of Geistlich Mucograft® Seal. The difference in size does not raise different

	Subject Devices	Predicate Devices (K192042, K140518, K102531, K073711)	Analysis
			questions of safety or effectiveness.
Single-Use	Yes	Same	Equivalent
Sterilization	Gamma	Same	Equivalent

Since prior clearance, the following minor changes were made:

- addition of a new 12 mm diameter Geistlich Mucograft® Seal configuration, and
- slight changes in the manufacturing processes for intermediate and final products.

These changes do not raise different questions of safety and effectiveness and is addressed by the information provided within the submission.

VII. Performance Data

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

Based on the results of risk assessment, no additional testing was required to support the new size configurations.

VIII. Conclusion

The subject devices are identical to the predicate device. The addition of a new 12 mm diameter for Geistlich Mucograft® Seal and slight changes in the manufacturing processes for the final product does not raise different questions of safety and effectiveness as demonstrated by risk assessment and verification and validation testing. Therefore, it is concluded that Geistlich Mucograft® and Geistlich Mucograft® Seal are substantially equivalent to the identified predicate devices.

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