Geistlich Pharma AG
% Janice M. Hogan
Regulatory Counsel
Hogan Lovells US LLP
1835 Market Street, 29th Floor
Philadelphia, Pennsylvania 19103

November 9, 2017

Re: K171050
Trade/Device Name: Geistlich Fibro-Gide
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: Class II
Product Code: NPL
Dated: October 12, 2017
Received: October 12, 2017

Dear Janice Hogan:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Mary S. Runner -S

for
Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental 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 on last page

510(k) Number *(if known)*

K171050

Device Name

Geistlich Fibro-Gide

Indications for Use *(Describe)*

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

GEISTLICH FIBRO-GIDE®

SPONSOR

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Switzerland

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Date Prepared: November 9, 2017

DEVICE NAME

Proprietary Name: Geistlich Fibro-Gide®
Common/Usual Names: Porcine Collagen Matrix
Classification Name: Barrier, animal source, intraoral (NPL)

PREDICATE DEVICES

Geistlich Mucograft® (K102531) (Primary predicate device)

Geistlich Mucograft® and Geistlich Mucograft® Seal (K140518) (Reference device)

Geistlich Mucograft® (K073711, K012423) (Reference devices)

GENOSS Collagen Membrane (K102307) (Reference device)

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 cross-linked. 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.

INTENDED USE AND 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.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Geistlich Fibro-Gide® and its primary predicate device Geistlich Mucograft® are implantable, collagen matrices (scaffolds) used in dental soft tissue augmentation procedures. Both devices consist of collagen fibers in a loose, porous arrangement to enable cell invasion and settlement, providing an environment to allow for soft tissue growth by using the patient's own healing capacities. Both devices are fully resorbable and do not require a second intervention for removal. Like its reference device, Geistlich Fibro-Gide® is cross-linked. The device dimensions are similar and both devices require adaptation to fit the defect size.

Bench testing was conducted to compare Geistlich Fibro-Gide® against its predicate device in terms of its appearance, porosity, amino acid and protein composition, capillarity and wettability, as well as trimming, suturing and degradation capabilities.

Comparison Table

Characteristic	**Geistlich Fibro-Gide®**	**Geistlich Mucograft (K102531 – Predicate device; K140518, K073711, K012423 – Reference devices)**
Intended Use		
Intended Use	Soft Tissue Augmentation	Soft Tissue Augmentation
Indications for Use	Geistlich Fibro-Gide® is	

Characteristic	Geistlich Fibro-Gide®	Geistlich Mucograft (K102531 – Predicate device; K140518, K073711, K012423 – Reference devices)
	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	• 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 • Recession defects for root coverage
Physical Characteristics		
Dimensions	15x20 mm, 20x40mm (thickness app. 6mm)	15x20 mm, 20x30 mm (K102531) 30x40 mm (K073711, K012423) (thickness app. 2.5 – 5 mm)
Form	Sponge-like matrix	Sponge-like matrix
Color	White to almost white	Almost white
Porosity	Very porous materials with average pore values of 90% or more. The average surface area and the bulk density of Geistlich Fibro-Gide® is almost identical to that of Geistlich Mucograft.	Very porous materials with average pore values of 90% or more. The average surface area and the bulk density of Geistlich Mucograft is almost identical to that of Geistlich Fibro-Gide.

Characteristic	**Geistlich Fibro-Gide®**	**Geistlich Mucograft (K102531 – Predicate device; K140518, K073711, K012423 – Reference devices)**
Capillarity and wettability	Spontaneously wettable and completely soaked in aqueous solution in less than one minute	Spontaneously wettable and completely soaked in aqueous solution in less than one minute
Cross-linking	Chemically cross-linked with EDC and NHS	Not chemically cross-linked
Easy to trim with surgical instruments (to fit a template)	Can be cut with surgical instruments	Can be cut with surgical instruments
Can be sutured	Can be fixed with sutures, as demonstrated by sutureability testing	Can be fixed with sutures, as demonstrated by sutureability testing
Composition Materials		
Raw Material	Porcine connective tissue, Porcine skin tissue	Porcine connective tissue, Porcine skin tissue
Composition	Porcine collagen: Product is produced from the same intermediate collagenous products	Porcine collagen: Product is produced from the same intermediate collagenous products
Collagen / Elastin	Major protein components Collagen I and Collagen III (no Collagen II) and Elastin	Major protein components Collagen I and Collagen III (no Collagen II) and Elastin
Amino Acid Composition	Very similar with equal amounts of amino acids	Very similar with equal amounts of amino acids
Fat	Trace (less than 0.5%)	Trace (less than 0.5%)
Glycosaminoglycans	Trace (less than 0.5%)	Trace (less than 0.5%)
Other proteins > 0.5%	None	None
pH	3-7	3-7

Characteristic	Geistlich Fibro-Gide®	Geistlich Mucograft (K102531 – Predicate device; K140518, K073711, K012423 – Reference devices)
Other Characteristics		
Source of raw material	Identical porcine tissue	Identical porcine tissue
Manufacture	Multistage validated, SOP controlled purification process	Multistage validated, SOP controlled purification process
Manufacturing conditions	Quality systems regulation (CFR Part 820)	Quality systems regulation (CFR Part 820)
Packaging	Conforms to ISO 11607, Parts 1 and 2. Sterile double layer packaging, including aluminum layer to protect against vapor penetration.	Conforms to ISO 11607, Parts 1 and 2. Sterile double layer packaging, in aluminum pouch to protect against vapor penetration.
Manufacture / Packaging location	Geistlich Pharma AG, Wolhusen, Switzerland	Geistlich Pharma AG, Wolhusen, Switzerland
Sterilization location	Synergy Health, Daeniken, Switzerland	Synergy Health, Daeniken, Switzerland
Sterility	Gamma irradiation SAL 10^{-6}; Device provided sterile, for single use only	Gamma irradiation SAL 10^{-6}; Device provided sterile, for single use only
User	Restricted to licensed dentists	Restricted to licensed dentists
Principles of Operation		
Principles of Operation	Implantable resorbable collagen matrix (scaffold) consisting of collagen fibers in a loose, porous	Implantable resorbable collagen matrix (scaffold) consisting of collagen fibers in a loose, porous

Characteristic	Geistlich Fibro-Gide®	Geistlich Mucograft (K102531 – Predicate device; K140518, K073711, K012423 – Reference devices)
	arrangement to enable cell invasion	arrangement to enable cell invasion
Performance Standards		
Conformity to standards	- ISO 10993-1 (Biocompatibility) - 10993-2 (Animal Welfare) - 10993-3 (Genotoxicity) - 10993-6 (Local Effects) - 10993-10 (Irritation / Sensitization) - 10993-11 (Systemic Tox.) - 10993-12 (Sample Prep.) - ISO 11137-1 (Sterilization Val) - ISO 11137-2 (Sterilization Dose) - ISO 11607-1 (Sterilization) - ISO 11607-2 (Sterilization) - ISO 11737-1 (Sterilization) - ISO 11737-2 (Sterilization) - ISO 11737-3 (Sterilization) - ISO 11607 (Packaging) - ISO 14698-1 (Cleanrooms) - ISO 14971 (Risk Management) - ISO 22441-1 (Animal Tissues) - ISO 22442-2 (Animal Tissues) - ISO 22442-3 (Viral Clearance) - USP 39 NF34 <151>: Pyrogen test - USP 39 NF34 85: Endotoxin test - ASTM F1980 (Accelerated Aging) - ASTM F2450-10 (Tissue Engineering)	- ISO 10993-1 (Biocompatibility) - 10993-2 (Animal Welfare) - 10993-3 (Genotoxicity) - 10993-6 (Local Effects) - 10993-10 (Irritation / Sensitization) - 10993-11 (Systemic Tox.) - 10993-12 (Sample Prep.) - ISO 11137-1 (Sterilization Val) - ISO 11137-2 (Sterilization Dose) - ISO 11607-1 (Sterilization) - ISO 11607-2 (Sterilization) - ISO 11737-1 (Sterilization) - ISO 11737-2 (Sterilization) - ISO 11737-3 (Sterilization) - ISO 11607 (Packaging) - ISO 14698-1 (Cleanrooms) - ISO 14971 (Risk Management) - ISO 22441-1 (Animal Tissues) - ISO 22442-2 (Animal Tissues) - ISO 22442-3 (Viral Clearance) - USP 39 NF34 <151>: Pyrogen test - USP 39 NF34 85: Endotoxin test - ASTM F1980 (Accelerated Aging) - ASTM F2450-10 (Tissue Engineering)

PERFORMANCE DATA

All relevant biocompatibility tests were conducted as required according to Guidance for Industry and Food and Drug Administration Staff *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process*. Testing included Cytotoxicity, Irritation, Sensitization, Acute System Toxicity, Genotoxicity, Subchronic System Toxicity, Chronic System Toxicity, Implantation, Pyrogenicity, and Leachables. Other testing included viral clearance studies and residual chemical testing and toxicological assessment. Results indicate that the device is biocompatible.

Test (Standard)	**Test method/ model**	**Results**
Cytotoxicity (ISO 10993-5)	In vitro mouse L929 fibroblast cell culture assay	Pass
Irritation (ISO 10993-10)	Intracutaneous reactivity in the rabbit	Pass
Sensitization (ISO 10993-10)	Guinea pig maximization test	Pass
Acute systemic toxicity (ISO 10993-11)	Acute systemic toxicity test in the mouse	Pass
Pyrogenicity (USP <151>)	Rabbit pyrogen test	Pass
Genotoxicity (ISO 10993-3)	Bacterial reverse mutagenicity assay in *Salmonella typhimurium* and *Escherichia coli* (Ames test)	Pass
	In vitro chromosomal aberration study in human lymphocytes	Pass
	Mouse peripheral blood micronucleus study	Pass
Local tissue response after implantation (ISO 10993-6)	4-week subcutaneous implantation in rats	Pass

	12-week subcutaneous implantation in rats	Pass
	26-week subcutaneous implantation in rats	Pass
Subchronic systemic toxicity (ISO 10993-11)	4-week subcutaneous implantation in rats, with systemic toxicity endpoint	Pass
Chronic systemic toxicity (ISO 10993-11)	26-week subcutaneous implantation in rats, with systemic toxicity endpoint	Pass
Leachables (ISO 10993-17)	GC/MS fingerprint and ICP analysis	Pass

Geistlich Fibro-Gide® was tested in a rat and in a dog study compliant with 21 CFR Part 58 to demonstrate substantial equivalence, safety and performance to its predicate device. The studies confirmed tissue integration, continuous resorption and comparable degradation rate of Geistlich Fibro-Gide® and the predicate devices. Further, the investigation of distal organs, hematologic parameters and clinical chemistries confirmed that the safety profile is acceptable. The dog study also investigated soft tissue augmentation and local tissue effects after several soft tissue augmentation periods in Geistlich Fibro-Gide® and the predicate device Geistlich Mucograft®. In all instances, the subject device was demonstrated to be substantially equivalent to the predicate device.

The clinical data from a controlled, parallel and randomized study in patients presenting insufficient soft tissue volume demonstrated product safety and effectiveness in the product's indications for use.

The biocompatibility testing, in combination with the bench testing, animal studies, and published clinical data included in this submission, demonstrates the substantial equivalence of Geistlich Fibro-Gide® to its predicate device, Geistlich Mucograft®.

CONCLUSION

Based on the data provided within this 510(k) submission as summarized above, it can be concluded that Geistlich Fibro-Gide® is substantially equivalent to the predicate device Geistlich Mucograft® with regard to intended use and indications for use, technological characteristics, including principles of operation, and performance characteristics as shown in a series of biocompatibility, bench, animal, and clinical testing. Thus, the subject device is substantially equivalent.