



August 29, 2019

Geistlich Pharma AG
% Roshana Ahmed
Associate Director, Regulatory Affairs
TELOS Partners LLC
571 Christina Lake Drive
Lakeland, Florida 33813

Re: K192042

Trade/Device Name: Geistlich Bio-Gide®, Geistlich Bio-Gide® Shape, Geistlich Bio-Gide® Compressed, Geistlich Bio-Gide® Perio, Geistlich Combi-Kit Collagen, Geistlich Perio-System Combi-Pack, Geistlich Mucograft® and Geistlich Mucograft® Seal

Regulation Number: 21 CFR 872.3930

Regulation Name: Bone Grafting Material

Regulatory Class: Class II

Product Code: NPL, NPM

Dated: July 31, 2019

Received: July 31, 2019

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 Srinivas Nandkumar, Ph.D.
Acting 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

Indications for Use

510(k) Number (if known)

K192042

Device Name

Geistlich Bio-Gide®

Indications for Use (Describe)

Geistlich Bio-Gide® is intended for the following uses:

- augmentation around implants placed in immediate extraction sockets;
- augmentation around implants placed in delayed extraction sockets;
- localized ridge augmentation for later implantation;
- alveolar ridge reconstruction for prosthetic treatment;
- filling of bone defects after root resection, cystectomy, removal of retained teeth;
- guided bone regeneration in dehiscence defects; and
- guided tissue regeneration procedures in periodontal defects.

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)

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

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Indications for Use

510(k) Number (if known)

K192042

Device Name

Geistlich Bio-Gide® Shape

Indications for Use (Describe)

Geistlich Bio-Gide® Shape is indicated for:

- augmentation around implants placed in immediate extraction sockets.
- augmentation around implants placed in delayed extraction sockets.
- localized ridge augmentation for later implantation.
- alveolar ridge reconstruction for prosthetic treatment.
- filling of bone defects after root resection, cystectomy, removal of retained teeth.
- guided bone regeneration in dehiscence defects.

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)

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Indications for Use

510(k) Number (if known)

K192042

Device Name

Geistlich Bio-Gide® Compressed

Indications for Use (Describe)

Geistlich Bio-Gide® Compressed is indicated for:

- augmentation around implants placed in immediate extraction sockets.
- augmentation around implants placed in delayed extraction sockets.
- localized ridge augmentation for later implantation.
- alveolar ridge reconstruction for prosthetic treatment.
- filling of bone defects after root resection, cystectomy, removal of retained teeth.
- guided bone regeneration in dehiscence defects.
- guided tissue regeneration procedures in periodontal defects.

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)

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Indications for Use

510(k) Number (if known)

K192042

Device Name

Geistlich Bio-Gide® Perio

Indications for Use (Describe)

Geistlich Bio-Gide® Perio is intended for the following uses:

- augmentation around implants placed in immediate extraction sockets;
- augmentation around implants placed in delayed extraction sockets;
- localized ridge augmentation for later implantation;
- alveolar ridge reconstruction for prosthetic treatment;
- filling of bone defects after root resection, cystectomy, removal of retained teeth;
- guided bone regeneration in dehiscence defects; and
- guided tissue regeneration procedures in periodontal defects.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

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Indications for Use

510(k) Number (if known)

K192042

Device Name

Geistlich Combi-Kit Collagen

Indications for Use (Describe)

Geistlich Bio-Gide® is intended for the following uses:

- augmentation around implants placed in immediate extraction sockets;
- augmentation around implants placed in delayed extraction sockets;
- localized ridge augmentation for later implantation;
- alveolar ridge reconstruction for prosthetic treatment;
- filling of bone defects after root resection, cystectomy, removal of retained teeth;
- guided bone regeneration in dehiscence defects; and
- guided tissue regeneration procedures in periodontal defects.

Geistlich Bio-Oss Collagen® is intended for the following uses:

- augmentation or reconstructive treatment of the alveolar ridge;
- filling of periodontal defects;
- filling of defects after root resection, apicoectomy, and cystectomy;
- filling of extraction sockets to enhance preservation of the alveolar ridge;
- elevation of the maxillary sinus floor;
- filling of periodontal defects in conjunction with products intended for Guided Tissue Regeneration (GTR) and Guided Bone Regeneration (GBR); and
- filling of peri-implant defects in conjunction with products intended for Guided Bone Regeneration (GBR).

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

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Indications for Use

510(k) Number (if known)

K192042

Device Name

Geistlich Perio-System Combi-Pack

Indications for Use (Describe)

Geistlich Bio-Gide® Perio is intended for the following uses:

- augmentation around implants placed in immediate extraction sockets;
- augmentation around implants placed in delayed extraction sockets;
- localized ridge augmentation for later implantation;
- alveolar ridge reconstruction for prosthetic treatment;
- filling of bone defects after root resection, cystectomy, removal of retained teeth;
- guided bone regeneration in dehiscence defects; and
- guided tissue regeneration procedures in periodontal defects.

Geistlich Bio-Oss Collagen® is intended for the following uses:

- augmentation or reconstructive treatment of the alveolar ridge;
- filling of periodontal defects;
- filling of defects after root resection, apicoectomy, and cystectomy;
- filling of extraction sockets to enhance preservation of the alveolar ridge;
- elevation of the maxillary sinus floor;
- filling of periodontal defects in conjunction with products intended for Guided Tissue Regeneration (GTR) and Guided Bone Regeneration (GBR); and
- filling of peri-implant defects in conjunction with products intended for Guided Bone Regeneration (GBR).

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)

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Indications for Use

510(k) Number (*if known*)

K192042

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)

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510(k) Summary

Geistlich Bio-Gide®

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: August 20, 2019

II. Device

Device Proprietary Name:	Geistlich Bio-Gide®
Common or Usual Name:	Resorbable Bilayer Membrane for Guided Tissue and Bone Regeneration
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 Bio-Gide®	K960724	Geistlich Pharma AG
	K042197	Geistlich Pharma AG
	K050446	Geistlich Pharma AG
	K112572	Geistlich Pharma AG

The following device is referenced within the submission:

- Geistlich Fibro-Gide, K171050, Geistlich Pharma AG

IV. Device Description

Geistlich Bio-Gide® is a pure collagen membrane with a bilayer structure. The porous surface (facing the bone) allows the ingrowth of bone forming cells, and the dense surface (facing the soft tissue) prevents the ingrowth of fibrous connective tissue into the bone defect. The membrane is made of collagen without further cross-linking, and is sterilized by gamma irradiation.

Geistlich Bio-Gide® is provided in the following sizes:

- 13 x 25 mm
- 25 x 25 mm
- 40 x 50 mm
- 16 x 22 mm as part of the Combi-Kit Collagen

V. Indications for Use

Geistlich Bio-Gide® is intended for the following uses:

- augmentation around implants placed in immediate extraction sockets;
- augmentation around implants placed in delayed extraction sockets;
- localized ridge augmentation for later implantation;
- alveolar ridge reconstruction for prosthetic treatment;
- filling of bone defects after root resection, cystectomy, removal of retained teeth;
- guided bone regeneration in dehiscence defects; and
- guided tissue regeneration procedures in periodontal defects.

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 device have identical final product specifications. A comparison of the subject and predicate device is provided in the table below.

	Subject Device	Predicate Device (K960724, K042197, K050446, K112572)
Material	Porcine	Same
Sizes	13 x 25 mm 25 x 25 mm 40 x 50 mm 16 x 22 mm	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 is addressed by the information provided within the submission.

VII. Performance Data

The following performance studies were conducted on the subject and predicate device to verify that material properties remained unchanged and support the substantial equivalence determination:

- elongation;
- suture pull-out test;
- swelling;
- Differential Scanning Calorimetry (DSC);
- collagenase digestion to assess degradation;
- Scanning Electron Microscopy (SEM) to assess optical differences; and
- viral safety evaluation per ICH Q5A(R1) and ISO 22442-3:2007 leveraged from K171050.

Biocompatibility, sterilization, shelf-life, and clinical performance testing from the applicant's own predicate devices were leveraged in support of substantial equivalence.

VIII. Conclusion

The subject device is identical to the predicate device. The addition of a raw material supplier does not raise different questions of safety and effectiveness. Therefore, it is concluded that Geistlich Bio-Gide[®] is substantially equivalent to the identified predicate device.

Geistlich Bio-Gide® Shape

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: August 20, 2019

II. Device

Device Proprietary Name:	Geistlich Bio-Gide® Shape
Common or Usual Name:	Collagen Resorbable Bilayer Membrane 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 Bio-Gide® Shape	K171643	Geistlich Pharma AG

The following device is referenced within the submission:

- Geistlich Fibro-Gide, K171050, Geistlich Pharma AG

IV. Device Description

Geistlich Bio-Gide® Shape is a pure collagen membrane with a bilayer structure. The porous surface (facing the bone) allows the ingrowth of bone forming cells into the membrane, and the dense surface (facing the soft tissue) prevents the ingrowth of fibrous connective tissue into the bone defect. The membrane is made of collagen without further cross-linking, and is sterilized by

gamma irradiation. The Geistlich Bio-Gide® Shape membrane has a pre-shaped form with a maximum width and height of 14 mm x 24 mm, respectively.

V. Indications for Use

Geistlich Bio-Gide® Shape is indicated for:

- augmentation around implants placed in immediate extraction sockets.
- augmentation around implants placed in delayed extraction sockets.
- localized ridge augmentation for later implantation.
- alveolar ridge reconstruction for prosthetic treatment.
- filling of bone defects after root resection, cystectomy, removal of retained teeth.
- guided bone regeneration in dehiscence defects.

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 device have identical final product specifications. A comparison of the subject and predicate device are provided in the table below.

	Subject Device	Predicate Device (K171643)
Material	Porcine collagen	Same
Sizes	14 x 24 mm (pre-shaped)	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 is addressed by the information provided within the submission.

VII. Performance Data

The following performance studies were conducted on representative product to verify that material properties remain unchanged and support the substantial equivalence determination:

- elongation;
- suture pull-out test;
- swelling;
- Differential Scanning Calorimetry (DSC);
- collagenase digestion to assess degradation;
- Scanning Electron Microscopy (SEM) to assess optical differences; and
- viral safety evaluation per ICH Q5A(R1) and ISO 22442-3:2007 leveraged from K171050.

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

VIII. Conclusion

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

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Geistlich Bio-Gide® Compressed

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: August 20, 2019

II. Device

Device Proprietary Name:	Geistlich Bio-Gide® Compressed
Common or Usual Name:	Collagen Resorbable Bilayer Membrane 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 device:

Product Name	510(k)	Applicant
Geistlich Bio-Gide® Compressed	K171643	Geistlich Pharma AG

The following device is referenced within the submission:

- Geistlich Fibro-Gide, K171050, Geistlich Pharma AG

IV. Device Description

Geistlich Bio-Gide® Compressed is a pure collagen membrane with a bilayer structure. The porous surface (facing the bone) allows the ingrowth of bone forming cells into the membrane, and the dense surface (facing the soft tissue) prevents the ingrowth of fibrous connective tissue into the bone defect. The membrane is made of collagen without further cross-linking, and is sterilized by gamma irradiation. The Geistlich Bio-Gide® Compressed membrane is available in two different sizes, 13 x 25 mm and 20 x 30 mm.

V. Indications for Use

Geistlich Bio-Gide[®] Compressed is indicated for:

- augmentation around implants placed in immediate extraction sockets.
- augmentation around implants placed in delayed extraction sockets.
- localized ridge augmentation for later implantation.
- alveolar ridge reconstruction for prosthetic treatment.
- filling of bone defects after root resection, cystectomy, removal of retained teeth.
- guided bone regeneration in dehiscence defects.
- guided tissue regeneration procedures in periodontal defects.

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 device have identical final product specifications. A comparison of the subject and predicate device is provided in the table below.

	Subject Device	Predicate Device (K171643)
Material	Porcine collagen	Same
Sizes	13 x 25 mm 20 x 30 mm	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 is addressed by the information provided within the submission.

VII. Performance Data

The following performance studies were conducted on representative product to verify that material properties remain unchanged and support the substantial equivalence determination:

- elongation;
- suture pull-out test;
- swelling;
- Differential Scanning Calorimetry (DSC);

- collagenase digestion to assess degradation;
- Scanning Electron Microscopy (SEM) to assess optical differences; and
- viral safety evaluation per ICH Q5A(R1) and ISO 22442-3:2007 leveraged from K171050.

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

VIII. Conclusion

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

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Geistlich Bio-Gide® Perio

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: August 20, 2019

II. Device

Device Proprietary Name:	Geistlich Bio-Gide® Perio
Common or Usual Name:	Collagen Resorbable Bilayer Membrane
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 Bio-Gide® Perio	K112575	Geistlich Pharma AG

The following device is referenced within the submission:

- Geistlich Fibro-Gide, K171050, Geistlich Pharma AG

IV. Device Description

Geistlich Bio-Gide® Perio is a pure collagen membrane with a bilayer structure and smoothed dense (cell-occlusive) surface. The modified surface makes the membrane somewhat stiffer in the dry state, and this facilitates cutting the membrane for periodontal applications. The porous surface (facing the bone) allows the ingrowth of bone forming cells, and the dense surface (facing the soft tissue) prevents the ingrowth of fibrous connective tissue into the defect. The membrane is made of collagen without further cross-linking, and is sterilized by gamma irradiation.

Preformed sterile templates are provided to simplify the cutting of the respective membrane shape. Four templates (uncoated Tyvek[®]) are packaged with Geistlich BioGide[®] Perio to serve as an aid to assist the clinician in trimming the Geistlich Bio-Gide[®] Perio membrane to fit the defect and are in varying shapes to fit the clinical need (e.g., rectangular, interproximal). The templates are packaged as an accessory product with Geistlich Bio-Gide[®] Perio.

V. Indications for Use

Geistlich Bio-Gide[®] Perio is intended for the following uses:

- augmentation around implants placed in immediate extraction sockets;
- augmentation around implants placed in delayed extraction sockets;
- localized ridge augmentation for later implantation;
- alveolar ridge reconstruction for prosthetic treatment;
- filling of bone defects after root resection, cystectomy, removal of retained teeth;
- guided bone regeneration in dehiscence defects; and
- guided tissue regeneration procedures in periodontal defects.

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 device have identical final product specifications. A comparison of the subject and predicate device are provided in the table below.

	Subject Device	Predicate Device (K112575)
Material	Porcine collagen	Same
Sizes	16 x 22 mm	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 is addressed by the information provided within the submission.

VII. Performance Data

The following performance studies were conducted on representative product to verify that material properties remain unchanged and support the substantial equivalence determination:

- elongation;
- suture pull-out test;
- swelling;
- Differential Scanning Calorimetry (DSC);
- collagenase digestion to assess degradation;
- Scanning Electron Microscopy (SEM) to assess optical differences; and
- viral safety evaluation per ICH Q5A(R1) and ISO 22442-3:2007 leveraged from K171050.

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

VIII. Conclusion

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

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Geistlich Combi-Kit Collagen

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: August 20, 2019

II. Device

Device Proprietary Name:	Geistlich Combi-Kit Collagen
Common or Usual Name:	Collagen Resorbable Bilayer Membrane Collagen Matrix
Classification Name:	Bone Grafting Material
Regulation Number:	872.3930
Product Code:	NPM
Device Classification	II

III. Predicate Device

Substantial equivalence is claimed to the following devices:

Product Name	510(k)	Applicant
Geistlich Combi-Kit Collagen	K112572	Geistlich Pharma AG
	K122894	Geistlich Pharma AG

The following device is referenced within the submission:

- Geistlich Fibro-Gide, K171050, Geistlich Pharma AG

IV. Device Description

Geistlich Combi-Kit Collagen is a convenience kit containing one unit of Geistlich Bio-Oss Collagen® and one unit of Geistlich Bio-Gide®. The two devices are packaged in double blisters in one package and then sterilized by gamma irradiation.

Geistlich Bio-Oss Collagen® is a combination of purified spongiosa (cancellous) natural bone mineral granules and 10% collagen fibers in a block form (100 mg) and is sterilized by gamma irradiation.

Geistlich Bio-Gide® is a pure collagen membrane with a bilayer structure. The porous surface (facing the bone) allows the ingrowth of bone forming cells, and the dense surface (facing the soft tissue) prevents the ingrowth of fibrous connective tissue into the bone defect. The membrane is made of collagen without further cross-linking, and is sterilized by gamma irradiation.

The size of the Geistlich Bio-Gide® bilayer membrane to be provided in the Geistlich Combi-Kit Collagen convenience kit is 16 mm x 22 mm.

V. Indications for Use

Geistlich Bio-Gide® is intended for the following uses:

- augmentation around implants placed in immediate extraction sockets;
- augmentation around implants placed in delayed extraction sockets;
- localized ridge augmentation for later implantation;
- alveolar ridge reconstruction for prosthetic treatment;
- filling of bone defects after root resection, cystectomy, removal of retained teeth;
- guided bone regeneration in dehiscence defects; and
- guided tissue regeneration procedures in periodontal defects.

Geistlich Bio-Oss Collagen® is intended for the following uses:

- augmentation or reconstructive treatment of the alveolar ridge;
- filling of periodontal defects;
- filling of defects after root resection, apicoectomy, and cystectomy;
- filling of extraction sockets to enhance preservation of the alveolar ridge;
- elevation of the maxillary sinus floor;
- filling of periodontal defects in conjunction with products intended for Guided Tissue Regeneration (GTR) and Guided Bone Regeneration (GBR); and
- filling of peri-implant defects in conjunction with products intended for Guided Bone Regeneration (GBR).

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 device have identical final product specifications. A comparison of the subject and predicate device is provided in the table below.

	Subject Device	Predicate Device (K112572 & K122894)
Format	Convenience Kit	Same
Kit Contents	Geistlich Bio-Oss Collagen [®] Geistlich Bio-Gide [®]	Same
Sizes	Geistlich Bio-Gide [®] : 16 x 22 mm	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 for the Geistlich Bio-Gide[®] component of the kit. This change does not raise different questions of safety and effectiveness and is addressed by the information provided within the submission.

VII. Performance Data

The following performance studies were conducted on representative product to verify that material properties remain unchanged and support the substantial equivalence determination:

- elongation;
- suture pull-out test;
- swelling;
- Differential Scanning Calorimetry (DSC);
- collagenase digestion to assess degradation;
- Scanning Electron Microscopy (SEM) to assess optical differences; and
- viral safety evaluation per ICH Q5A(R1) and ISO 22442-3:2007 leveraged from K171050.

Biocompatibility, sterilization, shelf-life, and clinical performance testing from the applicant's own predicate devices were leveraged in support of substantial equivalence.

VIII. Conclusion

The subject device is identical to the predicate device. The addition of a raw material supplier for Geistlich Bio-Gide® does not raise different questions of safety and effectiveness. Therefore, it is concluded that Geistlich Combi-Kit Collagen is substantially equivalent to the identified predicate device.

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Geistlich Perio-System Combi-Pack

I. Submitter

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Switzerland
Phone: +41 41 492 55 55

Contact Person: Marco Steiner, Deputy Director Regulatory Affairs
Date Prepared: August 20, 2019

II. Device

Device Proprietary Name:	Geistlich Perio-System Combi Pack
Common or Usual Name:	Collagen Resorbable Bilayer Membrane Collagen Matrix
Classification Name:	Bone Grafting Material
Regulation Number:	872.3930
Product Code:	NPM/NPL
Device Classification	II

III. Predicate Device

Substantial equivalence is claimed to the following devices:

Product Name	510(k)	Applicant
Geistlich Perio-System Combi Pack	K112575	Geistlich Pharma AG
	K122894	Geistlich Pharma AG

The following device is referenced within the submission:

- Geistlich Fibro-Gide, K171050, Geistlich Pharma AG

IV. Device Description

Geistlich Perio-System Combi-Pack is a convenience kit containing one unit of Geistlich Bio-Oss Collagen® and one unit of Geistlich Bio-Gide® Perio. Geistlich Bio-Oss Collagen® (sold either as an individual unit or as one of the components of Geistlich Perio-System Combi-Pack) is a combination of purified spongiosa (cancellous) natural bone mineral granules and 10% collagen fibers in a block form (100 mg) and is sterilized by gamma irradiation.

Geistlich Bio-Gide® Perio (sold either as an individual unit or as one of the components of Geistlich Perio-System Combi-Pack) is a pure collagen membrane with a bilayer structure and smoothed dense (cell-occlusive) surface. The modified surface makes the membrane somewhat stiffer in the dry state, and this facilitates cutting the membrane for periodontal applications. The porous surface (facing the bone) allows the ingrowth of bone forming cells, and the dense surface (facing the soft tissue) prevents the ingrowth of fibrous connective tissue into the defect. The membrane is made of collagen without further cross-linking, and is sterilized by gamma irradiation. The size of the Geistlich Bio-Gide® Perio bilayer membrane to be provided in the Geistlich Perio-System Combi-Pack convenience kit and as individual units is 16 mm x 22 mm.

Preformed sterile templates are provided to simplify the cutting of the respective membrane shape. Four templates (uncoated Tyvek®) are packaged with Geistlich Bio-Gide® Perio to serve as an aid to assist the clinician in trimming the Geistlich Bio-Gide® Perio membrane to fit the defect, and are in varying shapes to fit the clinical need (e.g., rectangular, interproximal). The templates are packaged as an accessory product with Geistlich Bio-Gide® Perio.

V. Indications for Use

Geistlich Bio-Gide® Perio is intended for the following uses:

- augmentation around implants placed in immediate extraction sockets;
- augmentation around implants placed in delayed extraction sockets;
- localized ridge augmentation for later implantation;
- alveolar ridge reconstruction for prosthetic treatment;
- filling of bone defects after root resection, cystectomy, removal of retained teeth;
- guided bone regeneration in dehiscence defects; and
- guided tissue regeneration procedures in periodontal defects.

Geistlich Bio-Oss Collagen® is intended for the following uses:

- augmentation or reconstructive treatment of the alveolar ridge;
- filling of periodontal defects;
- filling of defects after root resection, apicoectomy, and cystectomy;
- filling of extraction sockets to enhance preservation of the alveolar ridge;
- elevation of the maxillary sinus floor;
- filling of periodontal defects in conjunction with products intended for Guided Tissue Regeneration (GTR) and Guided Bone Regeneration (GBR); and
- filling of peri-implant defects in conjunction with products intended for Guided Bone Regeneration (GBR).

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 device have identical final product specifications. A comparison of the subject and predicate device are provided in the table below.

	Subject Device	Predicate Device (K112575 & K122894)
Format	Convenience Kit	Same
Kit Contents	Geistlich Bio-Oss Collagen [®] Geistlich Bio-Gide [®] Perio	Same
Sizes	Geistlich Bio-Gide [®] Perio: 16 x 22 mm	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 for the Geistlich Bio-Gide[®] Perio component of the kit. This change does not raise different questions of safety and effectiveness and is addressed by the information provided within the submission.

VII. Performance Data

The following performance studies were conducted on representative product to verify that material properties remain unchanged and support the substantial equivalence determination:

- elongation;
- suture pull-out test;
- swelling;
- Differential Scanning Calorimetry (DSC);
- collagenase digestion to assess degradation;
- Scanning Electron Microscopy (SEM) to assess optical differences; and
- viral safety evaluation per ICH Q5A(R1) and ISO 22442-3:2007 leveraged from K171050.

Biocompatibility, sterilization, shelf-life, and clinical performance testing from the applicant's own predicate devices were leveraged in support of substantial equivalence.

VIII. Conclusion

The subject device is identical to the predicate device. The addition of a raw material supplier for Geistlich Bio-Gide® does not raise different questions of safety and effectiveness. Therefore, it is concluded that Geistlich Perio-System Combi-Pack is substantially equivalent to the identified predicate device.

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Geistlich Mucograft® and Geistlich Mucograft® Seal

I. Submitter

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Phone: +41 41 492 55 55

Contact Person: Marco Steiner, Deputy Director Regulatory Affairs
Date Prepared: August 20, 2019

II. Device

Device Proprietary Name:	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	K140518	Geistlich Pharma AG
	K102531	Geistlich Pharma AG

The following device is referenced within the submission:

- Geistlich Fibro-Gide, K171050, 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 and 20 x 30 mm
- Geistlich Mucograft® Seal: 8 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 identical to the predicate devices 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 are provided in the table below.

	Subject Device	Predicate Device (K140518, K102531)
Material	Porcine collagen	Same
Sizes	Geistlich Mucograft®: 15 x 20 mm and 20 x 30 mm Geistlich Mucograft® Seal: 8 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 is addressed by the information provided within the submission.

The following performance studies were conducted on representative product to verify that material properties remain unchanged and support the substantial equivalence determination:

- elongation;
- suture pull-out test;
- swelling;
- Differential Scanning Calorimetry (DSC);
- collagenase digestion to assess degradation;
- Scanning Electron Microscopy (SEM) to assess optical differences; and
- viral safety evaluation per ICH Q5A(R1) and ISO 22442-3:2007 leveraged from K171050.

Biocompatibility, sterilization, shelf-life, and clinical performance testing from the applicant's own predicate devices were leveraged in support of substantial equivalence.

VIII. Conclusion

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

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