4/5/2022

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

Re: K212463
Trade/Device Name: Geistlich Bio-Gide, Geistlich Bio-Gide Shape, Geistlich Bio-Gide Compressed, Geistlich Bio-Gide Perio, Geistlich Combi-Kit Collagen and Geistlich Perio-System Combi Pack
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: Class II
Product Code: NPL, NPM
Dated: February 1, 2022
Received: February 1, 2022

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 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212463

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212463

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

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510(k) Number *(if known)*
K212463

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) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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Food and Drug Administration

Indications for Use

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Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212463

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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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212463

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) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212463

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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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: April 5, 2022

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 device:

- Geistlich Bio-Gide®, K192042, 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
- 30 x 40 mm
- 40 x 50 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.

VI. Comparison of Technological Characteristics

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

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

Technological comparison

	Subject Device	**Geistlich Bio-Gide® (K192042)**	**Analysis**
Material	Porcine collagen	Identical	The material of construction is identical.
Sizes	13 x 25 mm 25 x 25 mm 30 x 40 mm 40 x 50 mm 16 x 22 mm	Substantially equivalent	The offered sizes are similar.
Single-Use	Yes	Identical	Both products are single-use only.
Sterilization	Gamma	Identical	Both products use gamma irradiation.

The purpose of this submission is to notify the Agency of several minor changes to the product labeling and extension of the product range to include a 30 x 40 mm configuration which falls within the range of size configurations cleared under the predicate device. The differences between the subject and predicate device are addressed by the information provided within this submission.

VII. Performance Data

Non-clinical data was not deemed necessary to support the changes to the product labeling or extension to the product line.

Results from biocompatibility, sterilization, shelf-life, and bench and clinical performance studies from the applicant's own predicate devices (K192042) was leveraged in support of substantial equivalence. The following standards were utilized:

- ISO 10993-2018
- ISO 11137-1:2006
- ISO 11137-2:2013
- ISO 11137-3:2017

Data from fifteen (15) clinical studies involving 297 unique patients covering conditions from dehiscence type defects at dental implant sites to extraction sockets with and without bone resorption support that complete wound closure is not required for Geistlich Bio-Gide® when used in extraction sites and alveolar ridge defects with an average vertical defect length and alveolar ridge width up to 5.7 mm and 18 mm, respectively. In many of these studies, the defect was filled with bovine bone mineral before being covered with the collagen membrane under study. After a period of time, the defects were evaluated for new bone growth and defect size. Time to evaluation ranged from 4 months to 10 years, with 4 months being the most common length of time examined. The Bio-Gide collagen membrane successfully performed its intended function by creating space to allow for vertical bone fill to occur and providing better alveolar ridge preservation compared to controls.

VIII. Conclusion

The subject device is equivalent to the predicate device with respect to intended use and technological characteristics. 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: April 5, 2022

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 device:

- Geistlich Bio-Gide® Shape, K192042, 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; and
- guided bone regeneration in dehiscence defects.

VI. Comparison of Technological Characteristics

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

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

Technological comparison

	Subject Device	**Geistlich Bio-Gide® Shape (K192042)**	**Analysis**
Material	Porcine collagen	Identical	The material of construction is identical.
Sizes	14 x 24 mm (pre-shaped)	Identical	The offered sizes are identical.
Single-Use	Yes	Identical	Both products are single-use only.
Sterilization	Gamma	Identical	Both products use gamma irradiation.

The purpose of this submission is to notify the Agency of several minor changes to the product labeling. The differences between the subject and predicate device are addressed by the information provided within this submission.

VII. Performance Data

Non-clinical data was not deemed necessary to support the changes to the product labeling.

Results from biocompatibility, sterilization, shelf-life, and bench and clinical performance studies from the applicant's own predicate devices (K192042) was leveraged in support of substantial equivalence. The following standards were utilized:

- ISO 10993-2018
- ISO 11137-1:2006
- ISO 11137-2:2013
- ISO 11137-3:2017

Data from fifteen (15) clinical studies involving 297 unique patients covering conditions from dehiscence type defects at dental implant sites to extraction sockets with and without bone resorption support that complete wound closure is not required for Geistlich Bio-Gide® when used in extraction sites and alveolar ridge defects with an average vertical defect length and alveolar ridge width up to 5.7 mm and 18 mm, respectively. In many of these studies, the defect was filled with bovine bone mineral before being covered with the collagen membrane under study. After a period of time, the defects were evaluated for new bone growth and defect size. Time to evaluation ranged from 4 months to 10 years, with 4 months being the most common length of time examined. The Bio-Gide collagen membrane successfully performed its intended function by creating space to allow for vertical bone fill to occur and providing better alveolar ridge preservation compared to controls.

VIII. Conclusion

The subject device is equivalent to the predicate device with respect to intended use and technological characteristics. 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: April 5, 2022

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:

- Geistlich Bio-Gide® Compressed, K192042, 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, and
- guided tissue regeneration procedures in periodontal teeth.

VI. Comparison of Technological Characteristics

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

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

Technological comparison

	Subject Device	**Geistlich Bio-Gide® Compressed (K192042)**	**Analysis**
Material	Porcine collagen	Identical	The material of construction is identical.
Sizes	13 x 25 mm 20 x 30 mm	Identical	The offered sizes are identical.
Single-Use	Yes	Identical	Both products are single-use only.
Sterilization	Gamma	Identical	Both products use gamma irradiation.

The purpose of this submission is to notify the Agency of several minor changes to the product labeling. The differences between the subject and predicate device are addressed by the information provided within this submission.

VII. Performance Data

Non-clinical data was not deemed necessary to support the changes to the product labeling.

Results from biocompatibility, sterilization, shelf-life, and bench and clinical performance studies from the applicant's own predicate devices (K192042) was leveraged in support of substantial equivalence. The following standards were utilized:

- ISO 10993-2018
- ISO 11137-1:2006
- ISO 11137-2:2013
- ISO 11137-3:2017

Data from fifteen (15) clinical studies involving 297 unique patients covering conditions from dehiscence type defects at dental implant sites to extraction sockets with and without bone resorption support that complete wound closure is not required for Geistlich Bio-Gide® when used in extraction sites and alveolar ridge defects with an average vertical defect length and alveolar ridge width up to 5.7 mm and 18 mm, respectively. In many of these studies, the defect was filled with bovine bone mineral before being covered with the collagen membrane under study. After a period of time, the defects were evaluated for new bone growth and defect size. Time to evaluation ranged from 4 months to 10 years, with 4 months being the most common length of time examined. The Bio-Gide collagen membrane successfully performed its intended function by creating space to allow for vertical bone fill to occur and providing better alveolar ridge preservation compared to controls.

VIII. Conclusion

The subject device is equivalent to the predicate device with respect to intended use and technological characteristics. 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: April 5, 2022

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 device:

- Geistlich Bio-Gide® Perio, K192042, 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.

Pre-formed 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.

VI. Comparison of Technological Characteristics

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

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

Technological comparison

	Subject Device	**Geistlich Bio-Gide® Perio (K192042)**	**Analysis**
Material	Porcine collagen	Identical	The material of construction is identical.
Sizes	16 x 22 mm	Identical	The offered sizes are identical.
Single-Use	Yes	Identical	Both products are single-use only.
Sterilization	Gamma	Identical	Both products use gamma irradiation.

The purpose of this submission is to notify the Agency of several minor changes to the product labeling. The differences between the subject and predicate device are addressed by the information provided within this submission.

VII. Performance Data

Non-clinical data was not deemed necessary to support the changes to the product labeling.

Results from biocompatibility, sterilization, shelf-life, and bench and clinical performance studies from the applicant's own predicate devices (K192042) was leveraged in support of substantial equivalence. The following standards were utilized:

- ISO 10993-2018
- ISO 11137-1:2006
- ISO 11137-2:2013
- ISO 11137-3:2017

Data from fifteen (15) clinical studies involving 297 unique patients covering conditions from dehiscence type defects at dental implant sites to extraction sockets with and without bone resorption support that complete wound closure is not required for Geistlich Bio-Gide® when used in extraction sites and alveolar ridge defects with an average vertical defect length and alveolar ridge width up to 5.7 mm and 18 mm, respectively. In many of these studies, the defect was filled with bovine bone mineral before being covered with the collagen membrane under study. After a period of time, the defects were evaluated for new bone growth and defect size. Time to evaluation ranged from 4 months to 10 years, with 4 months being the most common length of time examined. The Bio-Gide collagen membrane successfully performed its intended function by creating space to allow for vertical bone fill to occur and providing better alveolar ridge preservation compared to controls.

VIII. Conclusion

The subject device is equivalent to the predicate device with respect to intended use and technological characteristics. 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: April 5, 2022

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/NPL
Device Classification	II

III. Predicate Device

Substantial equivalence is claimed to the following device:

- Geistlich Combi-Kit Collagen, K192042, 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 equivalent to the predicate device with respect to materials characteristics, manufacturing and sterilization methods, packaging, and size. Both the subject and predicate device have equivalent final product specifications. A comparison of the devices is provided in the table below.

	Subject Device	Predicate Device (K192042)	Analysis
Format	Convenience Kit	Identical	Both products are convenience kits.
Kit Contents	Geistlich Bio-Oss Collagen® Geistlich Bio-Gide®	Identical	The contents of the kits are identical.
Sizes	Geistlich Bio-Gide®: 16 x 22 mm	Identical	The product sizes are identical.
Single-Use	Yes	Identical	Both products are single-use only.
Sterilization	Gamma	Identical	Both products are gamma sterilized.

The purpose of this submission is to notify the Agency of several minor changes to the product labeling. The differences between the subject and predicate device are addressed by the information provided within this submission.

VII. Performance Data

Non-clinical data was not deemed necessary to support the changes to the product labeling.

Results from biocompatibility, sterilization, shelf-life, and bench and clinical performance studies from the applicant's own predicate devices (K192042) was leveraged in support of substantial equivalence. The following standards were utilized:

- ISO 10993-2018
- ISO 11137-1:2006
- ISO 11137-2:2013
- ISO 11137-3:2017

Data from fifteen (15) clinical studies involving 297 unique patients covering conditions from dehiscence type defects at dental implant sites to extraction sockets with and without bone resorption support that complete wound closure is not required for Geistlich Bio-Gide® when used in extraction sites and alveolar ridge defects with an average vertical defect length and alveolar ridge width up to 5.7 mm and 18 mm, respectively. In many of these studies, the defect was filled with bovine bone mineral before being covered with the collagen membrane under study. After a period of time, the defects were evaluated for new bone growth and defect size. Time to evaluation ranged from 4 months to 10 years, with 4 months being the most common length of time examined. The Bio-Gide collagen membrane successfully performed its intended function by creating space to allow for vertical bone fill to occur and providing better alveolar ridge preservation compared to controls.

VIII. Conclusion

The subject device is equivalent to the predicate device with respect to intended use and technological characteristics. 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: April 5, 2022

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:

- Geistlich Perio-System Combi Pack, K192042, 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 equivalent to the predicate device with respect to materials characteristics, manufacturing and sterilization methods, packaging, and size. Both the subject and predicate device have equivalent final product specifications. A comparison of the subject and predicate device is provided in the table below.

	Subject Device	Predicate Device (K192042)	Analysis
Format	Convenience Kit	Identical	Both products are convenience kits.
Kit Contents	Geistlich Bio-Oss Collagen® Geistlich Bio-Gide® Perio	Identical	The contents of the kits are identical.
Sizes	Geistlich Bio-Gide® Perio: 16 x 22 mm	Identical	The product sizes are identical.
Single-Use	Yes	Identical	Both products are single-use only.
Sterilization	Gamma	Identical	Both products are gamma sterilized.

The purpose of this submission is to notify the Agency of several minor changes to the product labeling. The differences between the subject and predicate device are addressed by the information provided within this submission.

VII. Performance Data

Non-clinical data was not deemed necessary to support the changes to the product labeling.

Results from biocompatibility, sterilization, shelf-life, and bench and clinical performance studies from the applicant's own predicate devices (K192042) was leveraged in support of substantial equivalence. The following standards were utilized:

- ISO 10993-2018
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- ISO 11137-2:2013
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Data from fifteen (15) clinical studies involving 297 unique patients covering conditions from dehiscence type defects at dental implant sites to extraction sockets with and without bone resorption support that complete wound closure is not required for Geistlich Bio-Gide® when used in extraction sites and alveolar ridge defects with an average vertical defect length and alveolar ridge width up to 5.7 mm and 18 mm, respectively. In many of these studies, the defect was filled with bovine bone mineral before being covered with the collagen membrane under study. After a period of time, the defects were evaluated for new bone growth and defect size. Time to evaluation ranged from 4 months to 10 years, with 4 months being the most common length of time examined. The Bio-Gide collagen membrane successfully performed its intended function by creating space to allow for vertical bone fill to occur and providing better alveolar ridge preservation compared to controls.

VIII. Conclusion

The subject device is equivalent to the predicate device with respect to intended use and technological characteristics. Therefore, it is concluded that Geistlich Perio-System Combi-Pack is substantially equivalent to the identified predicate device.

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