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

October 30, 2017

Re: K171643
Trade/Device Name: Geistlich Bio-Gide Shape, Geistlich Bio-Gide Compressed
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: Class II
Product Code: NPL
Dated: September 25, 2017
Received: September 25, 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

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)*

K171643

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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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: January 31, 2017
See PRA Statement on last page

510(k) Number *(if known)*

K171643

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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2. 510(k) Summary

GEISTLICH BIO-GIDE® SHAPE

SPONSOR

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Date Prepared: October 26, 2017

DEVICE NAME

Proprietary Name: Geistlich Bio-Gide® Shape
Common/Usual Names: Collagen Resorbable Bilayer Membrane
Classification Name: Bone Grafting Material
Product Code: NPL

PREDICATE DEVICE

Geistlich Bio-Gide® Perio (K112575)

REFERENCE DEVICE

Geistlich Bio-Gide® (K960724, K042197, K112572)

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 14mm x 24mm, respectively. With the exception of the size and shape, Geistlich Bio-Gide® Shape is the same as its predicate device, Geistlich Bio-Gide® Perio (K112575).

Available Products: Geistlich Bio-Gide® Shape 14 x 24 mm (pre-shaped form)

INTENDED 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.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS

Geistlich Bio-Gide® Shape has the similar technological characteristics (e.g., similar design, identical material) as the predicate device Geistlich Bio-Gide® Perio. Geistlich Bio-Gide® Shape has a pre-shaped form with a maximum width and height of 14 mm x 24 mm, respectively, whereas the predicate device, Geistlich Bio-Gide® Perio, is rectangular and has a size of 16 x 22 mm, this difference does not affect the determination of substantial equivalence, as supported by the performance data.

Characteristic	**Geistlich Bio-Gide® Perio (K112575)**	**Geistlich Bio-Gide® Shape (Proposed)**
Intended Use		
Intended Use/Indications for Use	Geistlich Bio-Gide® Perio is intended to be used 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.	Geistlich Bio-Gide® Shape is intended to be used 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.

Characteristic	Geistlich Bio-Gide® Perio (K112575)	Geistlich Bio-Gide® Shape (Proposed)
Physical characteristics		
Form	membrane	membrane
Dimensions	16 x 22 mm	14 x 24 mm (specifically shaped)
Composition Materials		
Native collagen	85 – 100%	85 – 100%
Amino Acid Composition	As standard	As standard
Fat	Not more than 1.0%	Not more than 1.0%
pH (finished product)	5.0 – 8.5	5.0 – 8.5
Manufacture		
Manufacturing conditions	Same manufacturing conditions	Same manufacturing conditions
Viral inactivation	Same viral inactivation step	Same viral inactivation step
Packaging	Double blister format. Inner and outer blister made of A-PET. Outer blister covered with polyethylene Tyvek foil.	Double blister format. Inner and outer blister made of A-PET. Outer blister covered with polyethylene Tyvek foil.

SUMMARY OF DATA TO SUPPORT SUBSTANTIAL EQUIVALENCE

Geistlich Bio-Gide® Shape is made of the same raw materials and manufactured with the same manufacturing process (except for the cutting step to create the modified shape) hence, the material properties are identical. Further, the same release testing as performed for the predicate is conducted for the subject device and includes determination of appearance, dry residue, sulphated ash, nitrogen total content, nitrogen amide content, fat content, pH value, native collagen, amino acid analysis, sterility test and bacterial endotoxins. Lot testing confirmed that the Geistlich Bio-Gide® Shape meets the specification and is equivalent to Geistlich Bio-Gide®. Usability tests with Geistlich Bio-Gide® Shape confirmed that the device is easy to use for procedures in extraction sockets. Sterilization validation of the subject device is based on the predicate and reference devices Geistlich Bio-Gide® Perio and Geistlich Bio-Gide® conducted according to the standards ISO 11137-1, ISO 11137-2, ISO 11137-3, ISO 11737-1 and ISO 11737-2, which showed that the devices meet the sterility specification. A viral clearance study in accordance with the requirements of ICH Q5A and ISO 22442-3 was conducted and confirmed sufficient viral clearance capacity of the manufacturing process of the Geistlich Bio-Gide® family of products.

The following biological risks were evaluated according to ISO 10993: cytotoxicity (ISO 10993-5), genotoxicity (ISO 10993-3), carcinogenicity (ISO 10993-3), irritation (ISO 10993-10), sensitization (ISO 10993-10), acute toxicity (ISO 10993-11), subchronic and chronic toxicity (ISO 10993-11) and implantation (local effects; ISO 10993-6). The results demonstrated that the device is biocompatible.

SUMMARY OF ANIMAL STUDY DATA

An *in vivo* animal study was conducted to evaluate the performance of Geistlich Bio-Gide® in facilitating guided bone regeneration around exposed implant threads (K960724). The results showed that treatment with Geistlich Bio-Gide® improved the decrease of defect size after 6 months, as evaluated histologically and by histomorphometry.

SUMMARY OF CLINICAL STUDY DATA

The clinical performance of the Geistlich Bio-Gide® family of products has been established based on clinical testing data from the K960724 and K042197 reference devices. A total of 75 patients were recruited in a study to examine the effectiveness and tolerability of Geistlich Bio-Gide® as a barrier membrane for guided bone regeneration in simultaneous implant placement. The results demonstrated the performance of Geistlich Bio-Gide® in combination with Geistlich Bio-Oss® for bone regeneration in defects around implants. No serious adverse event or antigenic reaction was observed. Only minor or moderate signs of inflammation, including pain, swelling, redness, hematoma or wound dehiscences were noted and were probably related to the surgical procedure.

Another clinical study involved 15 patients and the application of 16 Geistlich Bio-Gide membranes, which similarly showed that Geistlich Bio-Gide® can be used in defect filling in combination with bone grafting material Geistlich Bio-Oss®.

CONCLUSION

Geistlich Bio-Gide® Shape has same subset of indications and identical material properties as the predicate device, Geistlich Bio-Gide® Perio.

Thus, Geistlich Bio-Gide® Shape has the same intended use and similar technological characteristics as the predicate device.

Based on the data provided within this 510(k) submission as summarized above, it can be concluded that Geistlich Bio-Gide® Shape is substantially equivalent to the predicate device, Geistlich Bio-Gide® Perio (K112575), and the reference device, Geistlich Bio-Gide® (K112572).

GEISTLICH BIO-GIDE® COMPRESSED

SPONSOR

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Date Prepared: October 26, 2017

DEVICE NAME

Proprietary Name: Geistlich Bio-Gide® Compressed
Common/Usual Names: Collagen Resorbable Bilayer Membrane
Classification Name: Bone Grafting Material
Product Code: NPL

PREDICATE DEVICE

Geistlich Bio-Gide® Perio (K112575)

REFERENCE DEVICE

Geistlich Bio-Gide® (K960724, K042197, K112572)

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. With the exception of the size and a minor difference during manufacturing to mark the dense surface of the membrane, which should face the soft tissue, Geistlich Bio-Gide® Compressed is the same as its predicate device, Geistlich Bio-Gide® Perio.

Available Products:
Geistlich Bio-Gide® Compressed 13 x 25 mm
Geistlich Bio-Gide® Compressed 20 x 30 mm

INTENDED 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.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS

Geistlich Bio-Gide® Compressed has the similar technological characteristics (e.g., similar design, identical material) as the predicate device, Geistlich Bio-Gide® Perio. A manufacturing step has been added that marks the dense surface to indicate that it should face the soft tissue. In addition, the size of Geistlich Bio-Gide® Compressed has been modified. However, this difference does not affect the determination of substantial equivalence, as supported by the performance data and the company's cleared reference device

Characteristic	**Geistlich Bio-Gide® Perio (K112575)**	**Geistlich Bio-Gide® Compressed (Proposed)**
Intended Use		
Intended Use/Indications for Use	Geistlich Bio-Gide® Perio is intended to be used 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.	Geistlich Bio-Gide® Compressed is intended to be used 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.

Characteristic	Geistlich Bio-Gide® Perio (K112575)	Geistlich Bio-Gide® Compressed (Proposed)
Physical characteristics		
Form	membrane	membrane
Dimensions	16 x 22 mm	13 x 25 mm 20 x 30 mm
Composition Materials		
Native collagen	85 – 100%	85 – 100%
Amino Acid Composition	As standard	As standard
Fat	Not more than 1.0%	Not more than 1.0%
pH (finished product)	5.0 – 8.5	5.0 – 8.5
Manufacture		
Manufacturing conditions	Same manufacturing conditions	Same manufacturing conditions
Viral inactivation	Same viral inactivation step	Same viral inactivation step
Packaging	Double blister format. Inner and outer blister made of A-PET. Outer blister covered with polyethylene Tyvek foil.	Double blister format. Inner and outer blister made of A-PET. Outer blister covered with polyethylene Tyvek foil.

SUMMARY OF DATA TO SUPPORT SUBSTANTIAL EQUIVALENCE

Geistlich Bio-Gide® Compressed is made of the same raw materials and manufactured with the same manufacturing process (except for the cutting step and marking the device with “UP”) as the predicate device. Hence, the material properties are identical. Further, the same release testing is conducted for the subject and predicate devices, which includes determination of appearance, dry residue, sulphated ash, nitrogen total content, nitrogen amide content, fat content, pH value, native collagen, amino acid analysis, sterility test and bacterial endotoxins. Lot testing confirmed that Geistlich Bio-Gide® Compressed meets the specification and is equivalent to Geistlich Bio-Gide®. Usability tests confirmed that Geistlich Bio-Gide® Compressed has appropriate handling properties and is easy to use. Sterilization validation of the subject device is based on the predicate and reference devices Geistlich Bio-Gide® Perio and Geistlich Bio-Gide® conducted according to the standards ISO 11137-1, ISO 11137-2, ISO 11137-3, ISO 11737-1 and ISO 11737-2, which showed that the devices meet the sterility specification. A viral clearance study in accordance with the requirements of ICH Q5A and ISO 22442-3 was conducted and confirmed sufficient viral clearance capacity of the manufacturing process of the Geistlich Bio-Gide® family of products.

The following biological risks were evaluated according to ISO 10993: cytotoxicity (ISO 10993-5), genotoxicity (ISO 10993-3), carcinogenicity (ISO 10993-3), irritation (ISO 10993-10), sensitization (ISO 10993-10), acute toxicity (ISO 10993-11), subchronic and chronic toxicity (ISO

10993-11) and implantation (local effects; ISO 10993-6). The results demonstrated that the device is biocompatible.

SUMMARY OF ANIMAL STUDY DATA

An *in vivo* animal study was conducted to evaluate the performance of Geistlich Bio-Gide® in facilitating guided bone regeneration around exposed implant threads (K960724). The results showed that treatment with Geistlich Bio-Gide® improved the decrease of defect size after 6 months, as evaluated histologically and by histomorphometry.

SUMMARY OF CLINICAL STUDY DATA

The clinical performance of the Geistlich Bio-Gide® family of products has been established based on clinical testing data from the K960724 and K042197 reference devices. A total of 75 patients were recruited in a study to examine the effectiveness and tolerability of Geistlich Bio-Gide® as a barrier membrane for guided bone regeneration in simultaneous implant placement. The results demonstrated the performance of Geistlich Bio-Gide® in combination with Geistlich Bio-Oss® for bone regeneration in defects around implants. No serious adverse event or antigenic reaction was observed. Only minor or moderate signs of inflammation, including pain, swelling, redness, hematoma or wound dehiscences were noted and were probably related to the surgical procedure.

Another clinical study involved 15 patients and the application of 16 Geistlich Bio-Gide membranes, which similarly showed that Geistlich Bio-Gide® can be used in defect filling in combination with bone grafting material Geistlich Bio-Oss®.

In addition, the performance of Geistlich Bio-Gide® in guided tissue regeneration procedures in periodontal defects was evaluated in several clinical studies, as summarized below:

Defect Type	Subjects	Key Findings
Recession defects	20 patients, each contributing a pair of Miller Class I or II buccal gingival recessions	Treatment with Geistlich Bio-Gide® resulted in a significant gain of root coverage at 3 months and decrease of recess depth at 6 months.
Furcation defects	A total of 52 grade II mandibular molar furcation defects	The experimental group combined Bio-Oss® and Bio-Gide® presented with significantly greater pocket reduction, gain in clinical attachment level (CAL), vertical defect fill and horizontal defect fill compared to the control group (SCTG).
	21 patients with 31 furcation defects	There was a statistically significant improvement in most clinical indices for the Bio-Oss®/ Bio-Gide® group.

Intrabony defects	22 paired intrabony defects	Postoperative pocket depths, attachment levels and transoperative bone measurements were similar for control (open-flap debridement) and experimental (bovine porous bone mineral and Geistlich Bio-Gide®) sites.
	28 patients suffering from chronic periodontitis, and each of whom displayed one intrabony defect	No differences in any of the investigated parameters at baseline between Bio-Gide® treatment and access flap surgery (AFS). At 1 year after surgery both therapies resulted in significant gains of clinical attachment level (CAL) and probing depth (PD) reductions. The Bio-Gide® treatment group resulted in significantly higher CAL gains than treatment with AFS.
	124 patients with advanced chronic periodontitis, each with at least one intrabony defect of no less than 3mm	The Bio-Gide® test group showed a significantly higher gain in CAL and pocket reduction compared to the controls.
	4 intrabony defects, two received Geistlich Bio-Gide® alone and two were treated with a combination of Bio-Oss®/ Bio-Gide®	Both treatments were shown to significantly improve clinical probing depths and attachment levels, and the radiographic appearance suggested osseous fill. The regenerative effect was more pronounced with Bio-Gide®. Histologic evaluation revealed that both treatments produced new cementum with inserting collagen fibers and new bone formation on the surface of the graft particles.
	4 intrabony defects, two received Geistlich Bio-Gide® alone and two were treated with a combination of Bio-Oss®/ Bio-Gide®	Use of Bio-Oss® in combination with / Bio-Gide® resulted in a complete new attachment apparatus, evidencing periodontal regeneration that varied with defect morphology.

The above studies also showed a favorable safety profile for Geistlich Bio-Gide®, with no serious adverse events noted.

CONCLUSION

In summary, Geistlich Bio-Gide® Compressed has the same indications and identical material properties as the predicate device, Geistlich Bio-Gide® Perio. The sizes of Geistlich Bio-Gide® Compressed have been modified and a marking step is included during manufacture, but these differences are minor and do not affect the performance of the device, as supported by the testing conducted.

Based on the data provided within this 510(k) submission as summarized above, it can be concluded that Geistlich Bio-Gide® Compressed is substantially equivalent to the Geistlich Bio-Gide® Perio, the predicate device.