K112572

DEC 2 8 2011

2. 510(k) Summary

This 510(k) was submitted for two reasons: (1) to provide a convenience kit Geistlich Combi-Kit Collagen (composed of one unit of Geistlich Bio-Oss Collagen® and one unit of Geistlich Bio-Gide®), and (2) to modify the Instructions for Use of Geistlich Bio-Oss Collagen®, Geistlich Bio-Gide®, and Geistlich Bio-Oss®.

SPONSOR

Geistlich Pharma AG
Bahnhofstrasse 40
CH-6110 Wolhusen
Switzerland

Contact Person:	Daniel Kracov, Arnold & Porter, LLP
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Phone:	(202)942-5120
Date Prepared:	December 12, 2011

DEVICE NAME

Proprietary Name:	Geistlich Combi-Kit Collagen - Geistlich Bio-Oss Collagen® - Geistlich Bio-Gide® Geistlich Bio-Oss®
Common/Usual Names:	Natural Bone Grafting Material Plus Collagen Resorbable Bilayer Membrane for GTR/GBR
Classification Name:	Bone grafting material, animal source (NPM) Barrier, animal source, intraoral (NPL)

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PREDICATE DEVICES

Bio-Oss Collagen® (K092428, K033815, K974399)
Bio-Gide® (K050446, K042197, K960724)
Bio-Oss® and Bio-Oss® Blocks (K033815, K970321, K952618)

INTENDED 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;
- 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);
- Filling of peri-implant defects in conjunction with products intended for Guided Bone Regeneration (GBR).

Geistlich Bio-Oss® is intended for the following uses:
- Augmentation or reconstructive treatment of the alveolar ridge;
- Filling of infrabony 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);

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- Filling of peri-implant defects in conjunction with products intended for Guided Bone Regeneration (GBR).

The two products are being packaged together as a convenience kit for the ease of clinician use in regenerative procedures.

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 and is sterilized by gamma irradiation. Geistlich Bio-Oss Collagen® is the same as its predicate device, Bio-Oss Collagen®.

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 16mm x 22 mm. With the exception of the size of the membrane packaged in the convenience kit, Geistlich Bio-Gide® is the same as its predicate device, Bio-Gide®.

Geistlich Bio-Oss® spongiosa (cancellous) granules and Geistlich Bio-Oss® Block are natural non-antigenic porous bone mineral matrices. They are produced by removal of all organic components from bovine bone. Due to their natural structure, Geistlich Bio-Oss® and Geistlich Bio-Oss® Block, are physically and chemically comparable to the mineralized matrix of human bone. Geistlich Bio-Oss® is the same as its predicate device, Bio-Oss®.

TECHNOLOGICAL CHARACTERISTICS

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Geistlich Bio-Oss Collagen® and Geistlich Bio-Oss® have the same design, same chemical composition, and same materials as their respective predicate devices, and are substantially equivalent to their predicate devices, Bio-Oss Collagen® and Bio-Oss®.

Geistlich Bio-Gide® has the same design, same chemical composition, and same materials as its predicate device, Bio-Gide®. Although the dimensions of the membrane to be included in the Geistlich Combi-Kit Collagen convenience kit have been modified slightly, this difference does not change the intended use of the device. Thus, Geistlich Bio-Gide® is substantially equivalent to its predicate device, Bio-Gide®.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Geistlich Pharma AG
C/O Mr. Daniel A. Kravoc
Arnold & Porter LLP
555 Twelfth Street, N.W.
Washington, Distruct of Columbia 20004

DEC 2 8 2011

Re: K112572
Trade/Device Name: Geistlich Combi-Kit Collagen
Geistlich Bio-Oss®
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: II
Product Code: NPM
Dated: December 20, 2011
Received: December 21, 2011

Dear Mr. Kracov:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices /ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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 yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K 112572

Indications for Use

510(k) Number (if known): K112572

Device Name: Geistlich Combi-Kit Collagen

Indications For Use:
Geistlich Combi-Kit Collagen is a convenience kit that provides one (1) unit Geistlich Bio-Gide® resorbable bilayer collagen membrane and one (1) unit Geistlich Bio-Oss Collagen® block in one (1) package.

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).

Prescription Use _____ AND/OR Over-The-Counter Use _____ (Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K112572

Indications for Use

510(k) Number (if known):

Device Name: Geistlich Bio-Oss®

Indications For Use:

Geistlich Bio-Oss® is intended for the following uses:
- Augmentation or reconstructive treatment of the alveolar ridge;
- Filling of infrabony 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).

Prescription Use _____ AND/OR Over-The-Counter Use _____ (Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K112572