

510(k) Summary**FEB 15 2013****GEISTLICH BIO-OSS®****SPONSOR**

Geistlich Pharma AG
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Date Prepared: February 13, 2013

DEVICE NAME

Proprietary Name: Geistlich Bio-Oss®
Common/Usual Names: Bone Grafting Material
Classification Name: Bone grafting material, animal source (NPM)

PREDICATE DEVICES

Geistlich Bio-Oss® and Geistlich Bio-Oss® Blocks (K112572, K033815, K970321, K952618)

DEVICE DESCRIPTION

Geistlich Bio-Oss® spongiosa (cancellous) granules and Geistlich Bio-Oss® spongiosa (cancellous) Block (referred as Geistlich Bio-Oss®) are intended for filling and augmentation of bony voids and gaps in maxillofacial surgery, implantology, and periodontology according to the intended use of the product.

Geistlich Bio-Oss® is serving as a matrix consisting of interconnected macro- and micropores. The material is highly porous and has a large inner surface area.

Geistlich Bio-Oss® is a biocompatible bone mineral matrix and is manufactured from bovine bone in a validated multistage purification process to remove the organic components.

Due to the interconnected macro and microporous system the device is hydrophilic and easy to moisten.

Geistlich Bio-Oss[®] is packed in a double sterile barrier system consisting of a glass vial and an outer blister. Geistlich Bio-Oss is sterilized according to validated processes by γ -irradiation. It is available in the following sizes and amounts:

Product	Weight	Particle Size
Geistlich Bio-Oss [®] spongiosa (cancellous) granules	0.25 g	0.25 - 1.0 mm
Geistlich Bio-Oss [®] spongiosa (cancellous) granules	0.5 g	0.25 - 1.0 mm
Geistlich Bio-Oss [®] spongiosa (cancellous) granules	2.0 g	0.25 - 1.0 mm
Geistlich Bio-Oss [®] spongiosa (cancellous) granules	5.0 g	0.25 - 1.0 mm
Geistlich Bio-Oss [®] spongiosa (cancellous) granules	0.5 g	1.0 - 2.0 mm
Geistlich Bio-Oss [®] spongiosa (cancellous) granules	2.0 g	1.0 - 2.0 mm
Geistlich Bio-Oss [®] spongiosa (cancellous) block		1 x 1 x 2 cm (approx.)

INTENDED 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).

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS

Appearance: white granulate or white, porous block

Moisture: less than 5% (w./w.)

Calcium: 35%-40% (w./w.)

Phosphorous: 13.5% - 18.5% (w./w.)

SUMMARY OF DATA TO SUPPORT SUBSTANTIAL EQUIVALENCE

Geistlich Bio-Oss[®] from standard manufacturing lots was compared with Geistlich Bio-Oss[®] manufactured with the raw material from the alternative geographic source by means of X-ray diffraction analysis, Fourier Transform Infrared Spectroscopy and Mercury Intrusion Porosimetry.

The X-ray spectra of Geistlich Bio-Oss[®] manufactured with bovine bone from the alternative geographic source did not reveal any differences and confirmed that Geistlich Bio-Oss[®] is crystalline hydroxyapatite with no detectable impurities.

Fourier Transform Infrared Spectroscopy data was generated to determine the molecule structure characteristics of Geistlich Bio-Oss[®]. The data from regular manufacturing lots were equal to Geistlich Bio-Oss[®] manufactured from bovine bone of the alternative geographic source.

Mercury Intrusion Porosimetry revealed that porosity, specific pore surface area, bulk density and bimodal pore size distribution demonstrates that the micro and macro pores of Geistlich Bio-Oss[®] from regular manufacturing lots are identical to Geistlich Bio-Oss[®] manufactured from bovine bone of the alternative geographic source.

CONCLUSION

Results of the bench tests support that Geistlich Bio-Oss[®] is Substantially Equivalent to the identified predicate devices.

510(k) Summary

GEISTLICH BIO-OSS COLLAGEN®

SPONSOR

Geistlich Pharma AG
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Date Prepared: February 13, 2013

DEVICE NAME

Proprietary Name: Geistlich Bio-Oss Collagen®
Common/Usual Names: Bone Grafting Material Plus Collagen
Classification Name: Bone grafting material, animal source (NPM)

PREDICATE DEVICES

Geistlich Bio-Oss Collagen® (K112572, K092428, K033815, K974399)

DEVICE DESCRIPTION GBOC

Geistlich Bio-Oss Collagen® is a combination of purified spongiosa (cancellous) bone mineral granules (Geistlich Bio-Oss®) and 10% collagen fibers in a block form.

The collagen facilitates handling and application of Geistlich Bio-Oss Collagen® and acts to hold the Bio-Oss particles at the desired place. The consistency of this material readily allows to take the shape of the defect. The collagen component is resorbed after application.

Geistlich Bio-Oss Collagen® is intended for filling and augmentation of bony voids and gaps in maxillofacial surgery, implantology, and periodontology according to the intended use of the product.

Geistlich Bio-Oss Collagen® is serving as a matrix consisting of interconnected macro- and micropores. The material is highly porous and has a large inner surface area.

Geistlich Bio-Oss Collagen® is a biocompatible bone mineral matrix and is manufactured from bovine bone and collagen from connective tissue of pigs certified for human consumption according to a controlled and validated multistage purification process. From the bovine bone all organic components are removed.

Due to the interconnected macro and microporous system the device is hydrophilic and easy to moisten.

Geistlich Bio-Oss Collagen® is packed in a double sterile barrier system consisting of an inner and an outer blister. Geistlich Bio-Oss® is sterilized according to validated processes by γ -irradiation. It is available as part of two convenience kits and different sizes:

Single Products:

- 1 block 100 mg Geistlich Bio-Oss® spongiosa (cancellous) granules and 10% collagen
- 1 block 250 mg Geistlich Bio-Oss® spongiosa (cancellous) granules and 10% collagen
- 1 block 500 mg Geistlich Bio-Oss® spongiosa (cancellous) granules and 10% collagen

Convenience Kits:

- Geistlich Combi-Kit Collagen®
1 block 100 mg Geistlich Bio-Oss® spongiosa (cancellous) granules and 10% collagen, and 1 Geistlich Bio-Gide® membrane, 16 x 22 mm
- Geistlich Perio System Combi-Pack
1 block 100 mg Geistlich Bio-Oss® spongiosa (cancellous) granules and 10% collagen, and 1 Geistlich Bio-Gide® Perio membrane, 16 x 22 mm

INTENDED USE

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).

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS

Appearance: white sponge-like, hard pieces of customized size

Water: less than 8% (w./w.)

Calcium: 38%-42% (w./w.)

Phosphorous: 12.5% - 17.5% (w./w.)

SUMMARY OF DATA TO SUPPORT SUBSTANTIAL EQUIVALENCE

Geistlich Bio-Oss[®] from standard manufacturing lots was compared with Geistlich Bio-Oss[®] manufactured with the raw material from the alternative geographic source by means of X-ray diffraction analysis, Fourier Transform Infrared Spectroscopy and Mercury Intrusion Porosimetry.

The X-ray spectra of Geistlich Bio-Oss[®] manufactured from bovine bone of the alternative geographic source did not reveal any differences and confirmed that Geistlich Bio-Oss[®] is crystalline hydroxyapatite with no detectable impurities.

Fourier Transform Infrared Spectroscopy data was generated to determine the crystal structure, crystal size and molecule structure characteristics of Geistlich Bio-Oss[®]. The data from regular manufacturing lots were equal to Geistlich Bio-Oss[®] manufactured from bovine bone of the alternative geographic source.

Mercury Intrusion Porosimetry revealed that porosity, specific pore surface area, bulk density and bimodal pore size of Geistlich Bio-Oss[®] from regular manufacturing lots are identical to Geistlich Bio-Oss[®] manufactured from bovine bone of the alternative geographic source.

CONCLUSION

Geistlich Bio-Oss Collagen[®] is Substantially Equivalent to the identified predicate devices.



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

February 15, 2013

Geistlich Pharma AG
C/O Mr. Daniel A. Kracov
Arnold & Porter, Limited Liability Partnership
555 Twelfth Street, North West
WASHINGTON DC 20004-1206

Re: K122894

Trade/Device Name: Geistlich Bio-Oss[®] and Geistlich Bio-Oss Collagen[®]
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: II
Product Code: NPM
Dated: January 31, 2013
Received: February 1, 2013

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,


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

Enclosure

Indications for Use

510(k) Number (if known): (not yet known) K122894

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)

 Mary S. Runner
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Page 1 of 1

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

510(k) Number: K122894