K122894

510(k) Summary

FEB 15 2013

GEISTLICH BIO-OSS®

SPONSOR

Geistlich Pharma AG
Bahnhofstrasse 40
CH-6110 Wolhusen
Switzerland

Contact Person:	Daniel Kracov, Arnold & Porter, LLP Counsel to Geistlich Pharma AG
E-mail:	Daniel.Kracov@aporter.com
Phone:	202-942-5120
Fax:	202-942-5999
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
Bahnhofstrasse 40
CH-6110 Wolhusen
Switzerland

Contact Person:	Daniel Kracov, Arnold & Porter, LLP Counsel to Geistlich Pharma AG
E-mail:	Daniel.Kracov@aporter.com
Phone:	202-942-5120
Fax:	202-942-5999
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
- 1block 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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
2013.02.21
13:27:34 -05'00'

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 ___X___ 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
Susan Runner, DDS, MA 2013.02.15 09:45:55 -05'00'

Page 1 of __1__

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

510(k) Number: K122894

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

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Sincerely yours,

Mary S. Runner
Susan Runner, DDS, MPA
2013.02.21
13:27:34 -05'00'

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

Concurrence & Template History Page
[THIS PAGE IS INCLUDED IN IMAGE COPY ONLY]

Full Submission Number: K122894

For Office of Compliance Contact Information:

http://insideportlets.fda.gov:9010/portal/page?_pageid=197,415881&_dad=portal&_schema=PORTAL&org=318

For Office of Surveillance and Biometrics Contact Information:

http://insideportlets.fda.gov:9010/portal/page?_pageid=197,415881&_dad=portal&_schema=PORTAL&org=423

Digital Signature Concurrence Table	
Reviewer Sign-Off	
Branch Chief Sign-Off	
Division Sign-Off	Mary S. Runner Susan Runner, DDS, MA 2013.02.21 13:28:02 -05'00'

Template Name: K1(A) – SE after 1996

Template History:

Date of Update	By	Description of Update
7/27/09	Brandi Stuart	Added Updates to Boiler Table
8/7/09	Brandi Stuart	Updated HFZ Table
1/11/10	Diane Garcia	Liability/Warranty sentence added at bottom of 1st page
10/4/11	M. McCabe Janicki	Removed IFU sheet and placed in Forms
9/25/12	Edwena Jones	Added digital signature format
12/12/12	M. McCabe Janicki	Added an extra line between letter signature block and the word "Enclosure". Also, added a missing digit in 4-digit extension on letterhead zip code: "002" should be "0002".

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary S. Runner
Susan Runner, DDS, MA 2013.02.15
09:45:55 -05'00'

Page 1 of __1__

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

510(k) Number: K122894

4

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

November 23, 2012

GEISTLICH PHARMA AG
C/O ARNOLD & PORTER LLP
555 TWELFTH STREET, NW
WASHINGTON, DISTRICT OF COLUMBIA 20004-1206
ATTN: DANIEL A. KRACOV

510k Number: K122894

Product: GEISTLICH BIO-OSS, GEISTLICH B

On Hold As of 11/21/2012

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm.

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceProvisionsofFDAModernizationAct/ucm136685.htm.

In accordance with 21 CFR 807.87(l), FDA may consider a 510(k) to be withdrawn if the submitter fails to provide additional information within 30 days of an Additional Information (AI) request. FDA generally permits submitters additional time to respond to such requests. FDA intends to automatically grant a maximum of 180 calendar days from the date of the AI request, even if the submitter has not requested an extension. Therefore, submitters are no longer required to submit written requests for extension. However, submitters should be aware that FDA intends to issue a notice of withdrawal under 21 CFR 807.87(l) if FDA does not receive, in a submission to the appropriate Document Control Center, a complete response to all of the deficiencies in the AI request within 180 calendar days of the date that FDA issued that AI request. In this instance, pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

For further information regarding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee Amendments of 2012 (MDUFA III), to the Federal Food, Drug, and Cosmetic Act, you may refer to our guidance document entitled "Guidance for Industry and Food and Drug Administration Staff - FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Goals". You may review this document at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089735.htm>.

Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely yours,

Marjorie Shulman
Director, 510(k) Program
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

* * * COMMUNICATION RESULT REPORT (SEP. 25. 2012 9:59AM) * * *

FAX HEADER 1: FDA CDRH
FAX HEADER 2:

TRANSMITTED/STORED : SEP. 25. 2012 9:58AM

MODE	OPTION	ADDRESS	RESULT	PAGE
5456 MEMORY TX		RightFax	OK	2/2

REASON FOR ERROR
E-1) HANG UP OR LINE FAIL
E-2) BUSY
E-3) NO ANSWER
E-4) NO FACSIMILE CONNECTION

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

September 25, 2012

GEISTLICH PHARMA AG
C/O ARNOLD & PORTER LLP
555 TWELFTH STREET, NW
WASHINGTON, DISTRICT OF COLUMBIA 20004-1206
ATTN: DANIEL A. KRACOV

510k Number: K122894
Received: 9/21/2012
Product: GEISTLICH BIO-OSS, GEISTLICH B

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act(Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you when the processing of your 510(k) has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, the Food and Drug Amendments Act of 2007. Please visit our website at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm for more information regarding fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) needs to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm.

We remind you that Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the PHS Act by adding new section 402(j) (42 U.S.C. § 282(j)), which expanded the current database known as ClinicalTrials.gov to include mandatory registration and reporting of results for applicable clinical trials of human drugs (including biological products) and devices. Section 402(j) requires that a certification form http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm accompany 510(k)/HDE/PMA submissions. The agency has issued a draft guidance titled: "Certifications To Accompany Drug, Biological

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
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September 25, 2012

GEISTLICH PHARMA AG
C/O ARNOLD & PORTER LLP
555 TWELFTH STREET, NW
WASHINGTON, DISTRICT OF COLUMBIA 20004-1206
ATTN: DANIEL A. KRACOV

510k Number: K122894

Received: 9/21/2012

Product: GEISTLICH BIO-OSS, GEISTLICH B

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act(Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you when the processing of your 510(k) has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, the Food and Drug Amendments Act of 2007. Please visit our website at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm for more information regarding fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) needs to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm.

We remind you that Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the PHS Act by adding new section 402(j) (42 U.S.C. § 282(j)), which expanded the current database known as ClinicalTrials.gov to include mandatory registration and reporting of results for applicable clinical trials of human drugs (including biological products) and devices. Section 402(j) requires that a certification form http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm accompany 510(k)/HDE/PMA submissions. The agency has issued a draft guidance titled: "Certifications To Accompany Drug, Biological

Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007" http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134034.htm. According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

Please note the following documents as they relate to 510(k) review: 1) Guidance for Industry and FDA Staff entitled, "Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements". This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. Please refer to this guidance for information on a formalized interactive review process. 2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.html. In addition, the 510(k) Program Video is now available for viewing on line at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm070201.htm .

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm. If you have questions on the status of your submission, please contact DSMICA at (301)796-7100 or the toll-free number (800)638-2041 , or at their internet address http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm. If you have procedural questions, please contact the 510(k) Staff at (301)796-5640.

Sincerely,

510(k) Staff

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

September 21, 2012

USER FEE HOLD LETTER - HAVE NOT RECEIVED PAYM

GEISTLICH PHARMA AG
C/O ARNOLD & PORTER LLP
555 TWELFTH STREET, NW
WASHINGTON, DISTRICT OF COLUMBIA 20004-1206
ATTN: DANIEL A. KRACOV

510k Number: K122894

Received: 9/20/2012

User Fee ID Number: 6063939

Product: GEISTLICH BIO-OSS, GEIST

The Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

The Federal Food, Drug, and Cosmetic Act (the Act), as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) and the FDA Amendments Act of 2007 (FDAAA) (Public Law 110-85), authorizes FDA to collect user fees for certain types of 510(k) submissions. The submission cannot be accepted for review until the fee is paid in full ; therefore, the file has been placed on hold. When your user fee payment has been received , review of the 510(k) will resume as of that date. Alternatively, you may request withdrawal of your submission. You now have the option to pay online by credit card. We recommend this form of payment. Credit card payments are directly linked to your user fee cover sheet and are processed the next business day. You may also pay by check. If you choose to mail a check, please send a check to one of the addresses listed below:

By Regular Mail
Food and Drug Administration
P.O. Box 956733
St. Louis, MO 63195-6733.

By Private Courier(e.g.,Fed Ex, UPS, etc.)
U.S. Bank
956733
1005 Convention Plaza
St. Louis, MO 63101

The check should be made out to the Food and Drug Administration referencing the payment identification number, and a copy of the User Fee Cover sheet should be included with the check. A copy of the Medical Device User Fee Cover Sheet should be faxed to CDRH at (301)847-8120 referencing the 510(k) number if you have not already sent it in with your 510(k) submission. After the FDA has been notified of the receipt of your user fee payment, your 510(k) will be filed and the review will begin. If payment has not been received within 30 days, your 510(k) will be deleted from the system. Additional information on user fees and how to submit your user fee payment may be found at www.fda.gov/cdrh/mdufma/fy09userfee.html. In addition, the 510k Program Video is now available for viewing on line at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm070201.htm.

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, or HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.htm.

Please note that since your 510(k) has not been reviewed, additional information may be required during the review process and the file may be placed on hold once again. If you are unsure as to whether or not you need to file a 510k Submission with FDA or what type of submission to submit, you should first telephone the Division of Small Manufacturers, International and Consumer Assistance (DSMICA), for guidance at (301)796-7100 or its toll-fee number (800)638-2041, or contact them at their Internet address http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm, or you may submit a 513(g) request for information regarding classification to the Document Mail Center at the address above. If you have any questions concerning receipt of your payment, please contact Edwena Jones at Edwena.Jones@fda.hhs.gov or directly at (301)796-7200. If you have questions regarding the status of your 510(k) Submission, please contact DSMICA at the numbers or address above.

Sincerely yours,

Edwena Jones
Consumer Safety Technician
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

Mcdonald, Lisa *

From: Microsoft Outlook
To: daniel.kracov@aporter.com
Sent: Friday, September 21, 2012 9:02 AM
Subject: Relayed: K122894 ACK Letter

Delivery to these recipients or groups is complete, but no delivery notification was sent by the destination server:

daniel.kracov@aporter.com (daniel.kracov@aporter.com)

Subject: K122894 ACK Letter

86

K122894

ARNOLD & PORTER LLP

Daniel A. Kracov
Daniel.Kracov@aporter.com

+1 202.942.5000
+1 202.942.5999 Fax

555 Twelfth Street, NW
Washington, DC 20004-1206

CONFIDENTIAL
NOT FOR PUBLIC DISCLOSURE

September 20, 2012

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Document Control Center (HFZ-401)
10903 New Hampshire Avenue
Building 66, Room G609
Silver Spring, MD 20993-0002

Re: 510(k) Notification
Alternative Geographic Source for the Raw Material Bovine Bone used for the Manufacture of Geistlich Bio-Oss® and Geistlich Bio-Oss Collagen®

Dear Sir or Madam:

This premarket notification is submitted on behalf of Geistlich Pharma AG to provide for an alternative geographic source for the raw material bovine bone used in the production of Geistlich Bio-Oss® and Geistlich Bio-Oss Collagen®

(b)(4) Trade Secret Process - Product Specs

[redacted]

http://www.aphis.usda.gov/import_export/animals/animal_import/animal_imports_bse.shtml.

K18

Geistlich has concluded that using an alternative geographic source for the manufacture of Geistlich Bio-Oss® and Geistlich Bio-Oss Collagen® does not alter the performance characteristics and does also not raise new questions regarding safety and effectiveness of Geistlich Bio-Oss® or Geistlich Bio-Oss Collagen®.

- This premarket notification has been organized according to *Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s* (August 12, 2005).
- The *Guidance for Industry and FDA Staff -- Class II Special Controls Guidance Document: Dental Bone Grafting Material Devices* (April 28, 2005) was considered.
- The *Draft Guidance for Industry and Food and Drug Administration Staff -- The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]* (December 27, 2011) was considered.
- The *Guidance for FDA Reviewers and Industry: Medical Devices Containing Materials Derived from Animal Sources (Except for In Vitro Diagnostics)* (November 6, 1998) was considered.

For reviewer ease of use, the administrative information recommended in Appendix A of *Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s* (August 12, 2005) is provided below:

- Type of 510(k) Submission: Traditional 510(k)

- Common Name of Device:
  Geistlich Bio-Oss®: Natural Bone Grafting Material
  Geistlich Bio-Oss Collagen®: Natural Bone Grafting Material plus Collagen

- 510(k) Submitter: Geistlich Pharma AG

- Contact Person: Daniel A. Kracov, Arnold & Porter LLP
  Phone: (202)942-5120
  e-mail: Daniel.Kracov@aporter.com

- Preference for Continued Confidentiality: 21 CFR § 807.95

- Recommended Classification Recommendation: 21 CFR § 872.3930

- Class: Class II

- Panel: Dental Products Advisory Panel

- Product Code:
  Geistlich Bio-Oss Collagen® and Geistlich Bio-Oss®: NPM

- Prior Formal Correspondence: Not applicable

The table (below) provides an overview of the design and use of the devices, as recommended in Appendix A of *Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s* (August 12, 2005). The table is applicable to both devices Geistlich Bio-Oss® and Geistlich Bio-Oss Collagen®.

Design and Use of Geistlich Bio-Oss®: Natural Bone Grafting Material

Question	Yes	No
Is the device intended for prescription use (21 CFR Part 801, Subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR Part 801, Subpart C)?		X
Does the device contain components derived from a tissue or other biologic source?	X	
Is the device provided sterile?	X	
Is the device intended for single use?	X	
Is the device a reprocessed single use device?		X
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?		X
Does the submission include clinical information?		X
Is the device implanted?	X	

As noted at the beginning of this cover letter, this premarket notification is submitted to inform the FDA about Geistlich's intention to obtain bovine bone from an alternative geographic source – from New Zealand. No other changes will be made to the product, quality control procedures or manufacture.

Geistlich Pharma AG believes that it is appropriate and consistent with FDA guidance[2] to file one submission for the two medical devices Geistlich Bio-Oss® and Geistlich Bio-Oss Collagen®, because the underlying manufacturing process to process the bovine bone is identical for these products. Three general principles for bundling are discussed in this guidance, and this submission adheres to the first principle ("Bundling is appropriate for devices that present scientific and regulatory issues that can most efficiently be addressed during one review," and its three criteria):

- The supporting data are similar;
- Primarily one review division group (Dental Products Branch, CDRH) will be involved;
- The devices or indications for use are similar. Geistlich Bio-Oss® and Geistlich Bio-Oss Collagen® are used in regenerative procedures (e.g., Guided Bone Regeneration or GBR). Geistlich Bio-Oss® has the same indications for use statement as Geistlich Bio-Oss Collagen®.

We are providing an electronic copy per FDA's web instructions, and the electronic copy is an exact duplicate of the paper copy.

This document contains confidential commercial information and/or Trade Secrets that are exempt from disclosure under the Freedom of Information Act, 5 U.S.C. § 552, 21 U.S.C. § 301(y), 21 C.F.R. Part 20, and other applicable laws.

Sincerely,

Daniel A. Kracov
Counsel to Geistlich Pharma, AG

[2] *Guidance for Industry and FDA Staff: Bundling Multiple Devices or Multiple Indications in a Single Submission* (June 22, 2007).

Medical Device User Fee Cover Sheet (Form FDA 3601)

Form Approved: OMB No. 0910-511 Expiration Date: February 28, 2013. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER: (b)(4) Trade
Write the Payment Identification number on your check.

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)

ARNOLD AND PORTER
555 TWELFTH STREET, NW
WASHINGTON DC 20004-1202
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
(b)(4) Trade Secret
P P d t

2. CONTACT NAME
Joshua Glasser

2.1 E-MAIL ADDRESS
joshua.glasser@aporter.com

2.2 TELEPHONE NUMBER (include Area code)
202-942-5398

2.3 FACSIMILE (FAX) NUMBER (Include Area code)
202-942-5999

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/oc/mdufma

Select an application type:
[X] Premarket notification(510(k)); except for third party
[ ] 513(g) Request for Information
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)
[ ] Annual Fee for Periodic Reporting (APR)
[ ] 30-Day Notice

3.1 Select a center
[X] CDRH
[ ] CBER

3.2 Select one of the types below
[X] Original Application

Supplement Types:
[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)
[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
[X] NO, I am not a small business
4.1 If Yes, please enter your Small Business Decision Number:

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?
[X] YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)
[ ] NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.
[ ] This application is the first PMA submitted by a qualified small business, including any affiliates
[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only
[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).
[ ] YES [X] NO

PAPERWORK REDUCTION ACT STATEMENT
Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, 4th Floor Rockville, MD 20850
[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION
(b)(4) Trade Secret Process
18-Sep-2012

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

(b)(4) Trade Secret Process - Financial Specs

[redacted]

CDRH Premarket Review Submission Cover Sheet

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 0910-0120
Expiration Date: December 31, 2013
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
September 20, 2012	(b)(4) Trade	

SECTION A — TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☒ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify)*:
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission)*:
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☐ Yes ☒ No *(If Yes, please complete Section I, Page 5)*

SECTION B — SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name: Geistlich Pharma AG	Establishment Registration Number *(if known)*: 9614442		
Division Name *(if applicable)*:	Phone Number *(including area code)*: 011 41 41 492 55 55		
Street Address: Bahnhofstrasse 40	FAX Number *(including area code)*: 011 41 41 492 56 39		
City: Wolhusen	State / Province:	ZIP/Postal Code: CH-6110	Country: Switzerland
Contact Name: Marco Steiner			
Contact Title: Group Manager Regulatory Affairs	Contact E-mail Address: marco.steiner@geistlich.ch		

SECTION C — APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name: Arnold & Porter LLP			
Division Name *(if applicable)*:	Phone Number *(including area code)*: 202 942 5120		
Street Address: 555 Twelfth Street, NW	FAX Number *(including area code)*: 202 942 5999		
City: Washington	State / Province: District of Columbia	ZIP Code: 20004-1206	Country: USA
Contact Name: Daniel A. Kracov			
Contact Title:	Contact E-mail Address: Daniel.Kracov@aporter.com		

SECTION D1 — REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ New Device
- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site

- ☐ Process change:
  - ☐ Manufacturing ☐ Packaging
  - ☐ Sterilization
  - ☐ Other *(specify below)*

- ☐ Response to FDA correspondence:

- ☐ Change in design, component, or specification:
  - ☐ Software / Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*

- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*

- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager

- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment

- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address

☐ Other Reason *(specify)*:

SECTION D2 — REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access

- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor

- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final

- ☐ Response to FDA Letter Concerning:
  - ☐ Conditional Approval
  - ☐ Deemed Approved
  - ☐ Deficient Final Report
  - ☐ Deficient Progress Report
  - ☐ Deficient Investigator Report
  - ☐ Disapproval
  - ☐ Request Extension of Time to Respond to FDA
  - ☐ Request Meeting
  - ☐ Request Hearing

☐ Other Reason *(specify)*:

SECTION D3 — REASON FOR SUBMISSION - 510(k)

- ☐ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology

☒ Other Reason *(specify)*:

This premarket notification is to provide for an alternative geographic source for the raw material bovine bone used in the production of Geistlich Bio-Oss® (K120601, K112572, K033815, K970569) and Geistlich Bio-Oss Collagen® (K112572, K092428, K974399) (and Geistlich Bio-Oss Collagen® as part of Geistlich's convenience kits Combi-Kit Collagen (K112572) and Perio System Combi Pack (K112575)).

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	NPM	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

☒ 510 (k) summary attached
☐ 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K112572, K112575	1	Geistlich Bio-Oss, Bio-Oss Collagen, Combi-Kit Collagen and Perio-System Combi Pack	1	Geistlich Pharma AG
2	K033815	2	Bio-Oss, Bio-Oss Collagen	2	Geistlich Pharma AG
3	K092428	3	Bio-Oss Collagen	3	Geistlich Pharma AG
4	K970569	4	Bio-Oss	4	Geistlich Pharma AG
5	K974399	5	Bio-Oss Collagen	5	Geistlich Pharma AG
6	K120601	6	Geistlich Bio-Oss Pen	6	Geistlich Pharma AG

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

dental, animal source

	Trade or Proprietary or Model Name for This Device		Model Number
1	Geistlich Bio-Oss	1	20111, 20112, 20113, 20114, 20121, 20122, 20131
2	Geistlich Bio-Oss Collagen	2	20141, 20142, 20143
3	Geistlich Combi-Kit Collagen	3	20146
4	Geistlich Perio System Combi Pack	4	20147
5	Geistlich Bio-Oss Pen	5	20115

FDA document numbers of all prior related submissions *(regardless of outcome)*

1 K120601	2 K112575	3 K112572	4 K092428	5 K033815	6 K974399
7 K970569	8	9	10	11	12

Data Included in Submission

☒ Laboratory Testing ☐ Animal Trials ☐ Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
NPM	21 C.F.R. § 872.3930	☐ Class I ☒ Class II
Classification Panel		☐ Class III ☐ Unclassified
Dental Devices Panel		

Indications *(from labeling)*

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

Geistlich Bio-Oss Collagen is intended for the same uses as Geistlich Bio-Oss, except that its second indication refers to "periodontal defects" rather than "infrabony periodontal defects."

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number *(if known)*

SECTION H — MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number 9614442	☒ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name Geistlich Pharma AG		Establishment Registration Number 9614442	
Division Name *(if applicable)*		Phone Number *(including area code)* 011 41 41 492 55 55	
Street Address Bahnhofstrasse 40		FAX Number *(including area code)* 011 41 41 492 56 39	
City Wolhusen		State / Province	ZIP Code CH-6110 / Country Switzerland
Contact Name Marco Steiner	Contact Title Group Manager Regulatory Affairs	Contact E-mail Address marco.steiner@geistlich.ch	

(b)(4) Trade Secret Process - Product Specs

[redacted]

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name *(if applicable)*		Phone Number *(including area code)*	
Street Address		FAX Number *(including area code)*	
City		State / Province	ZIP Code / Country
Contact Name	Contact Title	Contact E-mail Address	

SECTION I — UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.

1	Standards No.	Standards Organization	Standards Title	Version	Date
2	Standards No.	Standards Organization	Standards Title	Version	Date
3	Standards No.	Standards Organization	Standards Title	Version	Date
4	Standards No.	Standards Organization	Standards Title	Version	Date
5	Standards No.	Standards Organization	Standards Title	Version	Date
6	Standards No.	Standards Organization	Standards Title	Version	Date
7	Standards No.	Standards Organization	Standards Title	Version	Date

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

ARNOLD & PORTER LLP

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555 Twelfth Street, NW
Washington, DC 20004-1206

CONFIDENTIAL
NOT FOR PUBLIC DISCLOSURE

September 20, 2012

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Document Control Center (HFZ-401)
10903 New Hampshire Avenue
Building 66, Room G609
Silver Spring, MD 20993-0002

Re: 510(k) Notification
Alternative Geographic Source for the Raw Material Bovine Bone used for the Manufacture of Geistlich Bio-Oss® and Geistlich Bio-Oss Collagen®

Dear Sir or Madam:

This premarket notification is submitted on behalf of Geistlich Pharma AG to provide for an alternative geographic source for the raw material bovine bone used in the production of Geistlich Bio-Oss® and Geistlich Bio-Oss Collagen®.

(b)(4) Trade Secret Process - Product Specs

[redacted]

[1] *http://www.aphis.usda.gov/import_export/animals/animal_import/animal_imports_bse.shtml.*

Geistlich has concluded that using an alternative geographic source for the manufacture of Geistlich Bio-Oss® and Geistlich Bio-Oss Collagen® does not alter the performance characteristics and does also not raise new questions regarding safety and effectiveness of Geistlich Bio-Oss® or Geistlich Bio-Oss Collagen®.

- This premarket notification has been organized according to *Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s* (August 12, 2005).
- The *Guidance for Industry and FDA Staff -- Class II Special Controls Guidance Document: Dental Bone Grafting Material Devices* (April 28, 2005) was considered.
- The *Draft Guidance for Industry and Food and Drug Administration Staff -- The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]* (December 27, 2011) was considered.
- The *Guidance for FDA Reviewers and Industry: Medical Devices Containing Materials Derived from Animal Sources (Except for In Vitro Diagnostics)* (November 6, 1998) was considered.

For reviewer ease of use, the administrative information recommended in Appendix A of *Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s* (August 12, 2005) is provided below:

- Type of 510(k) Submission: Traditional 510(k)

- Common Name of Device:
  Geistlich Bio-Oss®: Natural Bone Grafting Material
  Geistlich Bio-Oss Collagen®: Natural Bone Grafting Material plus Collagen

- 510(k) Submitter: Geistlich Pharma AG

- Contact Person: Daniel A. Kracov, Arnold & Porter LLP
  Phone: (202)942-5120
  e-mail: Daniel.Kracov@aporter.com

- Preference for Continued Confidentiality: 21 CFR § 807.95

- Recommended Classification Recommendation: 21 CFR § 872.3930

- Class: Class II

- Panel: Dental Products Advisory Panel

- Product Code:
  Geistlich Bio-Oss Collagen® and Geistlich Bio-Oss®: NPM

- Prior Formal Correspondence: Not applicable

The table (below) provides an overview of the design and use of the devices, as recommended in Appendix A of *Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s* (August 12, 2005). The table is applicable to both devices Geistlich Bio-Oss® and Geistlich Bio-Oss Collagen®.

Design and Use of Geistlich Bio-Oss®: Natural Bone Grafting Material

Question	**Yes**	**No**
Is the device intended for prescription use (21 CFR Part 801, Subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR Part 801, Subpart C)?		X
Does the device contain components derived from a tissue or other biologic source?	X	
Is the device provided sterile?	X	
Is the device intended for single use?	X	
Is the device a reprocessed single use device?		X
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?		X
Does the submission include clinical information?		X
Is the device implanted?	X	

As noted at the beginning of this cover letter, this premarket notification is submitted to inform the FDA about Geistlich's intention to obtain bovine bone from an alternative geographic source (b)(4) Trade Secret Process Product. No other changes will be made to the product, quality control procedures or manufacture.

Geistlich Pharma AG believes that it is appropriate and consistent with FDA guidance[2] to file one submission for the two medical devices Geistlich Bio-Oss® and Geistlich Bio-Oss Collagen®, because the underlying manufacturing process to process the bovine bone is identical for these products. Three general principles for bundling are discussed in this guidance, and this submission adheres to the first principle ("Bundling is appropriate for devices that present scientific and regulatory issues that can most efficiently be addressed during one review," and its three criteria):

- The supporting data are similar;
- Primarily one review division group (Dental Products Branch, CDRH) will be involved;
- The devices or indications for use are similar. Geistlich Bio-Oss® and Geistlich Bio-Oss Collagen® are used in regenerative procedures (e.g., Guided Bone Regeneration or GBR). Geistlich Bio-Oss® has the same indications for use statement as Geistlich Bio-Oss Collagen®.

We are providing an electronic copy per FDA's web instructions, and the electronic copy is an exact duplicate of the paper copy.

This document contains confidential commercial information and/or Trade Secrets that are exempt from disclosure under the Freedom of Information Act, 5 U.S.C. § 552, 21 U.S.C. § 301(y), 21 C.F.R. Part 20, and other applicable laws.

Sincerely,

Daniel A. Kracov
Counsel to Geistlich Pharma, AG

[2] *Guidance for Industry and FDA Staff: Bundling Multiple Devices or Multiple Indications in a Single Submission* (June 22, 2007).

Table of Contents

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(b)(4) Trade Secret Process - Product Specs

[redacted]

1.) Indications for Use Statement

The Indication for Use Statement for Geistlich Bio-Oss® and Geistlich Bio-Oss Collagen® are on the following pages.

Indications for Use

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

Page 1 of __1___

Indications for Use

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

Device Name: Geistlich Bio-Oss Collagen®

Indications For 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).

Prescription Use ___**X**___ 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)

Page 1 of __1___

2.) 510(k) Summary

2.1 GEISTLICH BIO-OSS®

2.1 GEISTLICH BIO-OSS®

SPONSOR

Geistlich Pharma AG
Bahnhofstrasse 40
CH-6110 Wolhusen
Switzerland

Contact Person:	Daniel Kracov, Arnold & Porter, LLP
E-mail:	Daniel.Kracov@aporter.com
Phone:	202-942-5120
Fax:	202-942-5999
Date Prepared:	10th Sept., 2012

DEVICE NAME

Proprietary Name:	Geistlich Bio-Oss®
Common/Usual Names:	Natural 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 for blood clot stabilization and cell and tissue integration. The material is highly porous and has a large inner surface area enabling settlement of new cells and thereby promoting vascularization and formation of new bone. Geistlich Bio-Oss® is physically, chemically as well as structurally comparable to the mineralized matrix of human bone.

Geistlich Bio-Oss® is a natural non-antigenic fully biocompatible bone mineral matrix and is manufactured from bovine bone in a validated multistage purification process to remove the organic components without altering the natural structure of the inorganic bone matrix.

Due to the interconnected macro and microporous system the device is highly 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.

2.2 GEISTLICH BIO-OSS COLLAGEN®

2.2 GEISTLICH BIO-OSS COLLAGEN®

Geistlich Pharma

SPONSOR

Geistlich Pharma AG
Bahnhofstrasse 40
CH-6110 Wolhusen
Switzerland

Contact Person: Daniel Kracov, Arnold & Porter, LLP
E-mail: Daniel.Kracov@aporter.com
Phone: 202-942-5120
Fax: 202-942-5999
Date Prepared: 10th Sept., 2012

DEVICE NAME

Proprietary Name: Geistlich Bio-Oss Collagen®

Common/Usual Names: Natural 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 rapidly 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 for blood clot stabilization and cell and tissue integration. The material is highly porous and has a large inner surface area enabling settlement of new cells and thereby promoting vascularization and formation of new bone. The natural bone mineral granules are physically, chemically as well as structurally comparable to the mineralized matrix of human bone

Geistlich Bio-Oss Collagen®is a natural non-antigenic fully biocompatible bone mineral matrix and is manufactured from bovine bone and collagen from connective

tissue of pigs fit certified for human consumption according to a controlled and validated multistage purification process. From the bovine bone all organic components are removed without altering the natural structure of the inorganic bone matrix

Due to the interconnected macro and microporous system the device is highly 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
- 1block 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.

3.) Truthful and Accurate Statement

Please find the signed original of the *Truthful and Accurate* Statement on the following page.

Geistlich
Pharma

Truthful and Accurate Statement

I certify that, in my capacity as Chief Executive Officer (CEO) of Geistlich Pharma AG, I believe to the best of my knowledge, that all data and information submitted in this premarket notification are truthful and accurate and that no material fact has been omitted.

10 Sep 2012

Paul Note [Date]

(Premarket Notification [510(k)] Number)

4.) Class III Summary and Certification

A Class III Summary and Certification is not required. Both Geistlich Bio-Oss® and Geistlich Bio-Oss Collagen®, are Class II devices (per 21 CFR § 872.3930 bone grafting material) with product codes NPM.

5.) Financial Certification or Disclosure Statement

Clinical studies are not included in this 510(k) submission, and this requirement is not applicable.

6.) Declarations of Conformity and Summary Reports

This submission is a traditional 510(k), and not an abbreviated 510(k). There are no Declarations of Conformity or Summary Reports included in this submission.

7.) Executive Summary

Geistlich Bio-Oss® and Geistlich Bio-Oss Collagen® are medical devices used in dental applications for guided bone and tissue regeneration. Geistlich Bio-Oss® consists of highly purified bone mineral and is available as a block or as granules. It serves as a natural non-antigenic porous bone mineral matrix for blood clot stabilization, cell and tissue integration for regeneration and augmentation of bone. Geistlich Bio-Oss Collagen® consists of Geistlich Bio-Oss® granules and 10% collagen of porcine origin.

This premarket notification is submitted to receive FDA clearance for an alternative geographic source for the raw material bovine bone used in the production of Geistlich Bio-Oss® and Geistlich Bio-Oss Collagen®.

(b)(4) Trade Secret Process - Product Specs

[redacted]

USDA provides a list with countries where BSE exists (*Countries where BSE exists* or *Countries presenting an undue risk of BSE)* on its website (*Countries / Regions Affected with Bovine Spongiform Encephalopathy (BSE)*). (b)(4) is not among the countries presented on this list.[1]

(b)(4) Trade Secret Process - Product Specs

[redacted]

Geistlich meets the FDA recommendations defined in the guidance document *Guidance for FDA Reviewers and Industry: Medical Devices Containing Materials Derived from Animal Sources (Except for In Vitro Diagnostics)*, November 6, 1998 regarding the identification, country of origin, traceability and bovine tissue source of the raw material.

[1] *http://www.aphis.usda.gov/import_export/animals/animal_import/animal_imports_bse.shtml*

Geistlich conducted extensive comparison studies (see Section 15 Performance Testing – Bench) and the physical properties of Geistlich Bio-Oss® manufactured (b)(4) Trade Secret Process - Product Specs [redacted] and Geistlich Bio-Oss® manufactured from [redacted] were compared by using X-ray diffraction analysis, HG pressure porosimetry and Fourier transform infrared spectroscopy.

Based on the generated data it was concluded that the relevant physical properties of Geistlich Bio-Oss® manufactured with (b)(4) Trade Secret Process - Product Specs [redacted] (b)(4) [redacted] are identical to Geistlich Bio-Oss® manufactured with (b)(4) Trade Secret [redacted] (b)(4) Trade Secret Process - Product Specs [redacted] The data generated for Geistlich Bio-Oss® is equally relevant for Geistlich Bio-Oss Collagen®. Geistlich Bio-Oss Collagen® is a combination of purified spongiosa (cancellous) natural 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 collagen component is rapidly resorbed after application.

Geistlich has imposed stringent Quality Controls for sourcing, processing, cleaning, storage, shipment, record keeping and other procedures at the raw material supplier in (b)(4) Trade Secret Process - Product Specs [redacted] and signed Quality Agreements are in place. Only defined raw material (bone disks of disarticulated bones) will be used for Geistlich which will be used in the further production of Geistlich Bio-Oss® at the Geistlich facilities in Wolhusen, Switzerland (for more detailed information see Section 18.1).

Systems are in place which guarantee full traceability from customer to the batch of raw material and further up to the animal farm from where the animals were taken for slaughtering. And conversely from the batch of raw material that was used in production to the customer that purchased Geistlich Bio-Oss® or Geistlich Bio-Oss Collagen® (for more detailed information see Section 18.1).

Geistlich conducts on site Audits at (b)(4) Trade Secret Process - Product Specs [redacted] facilities regularly to control compliance of the supplier to the defined requirements (for more detailed information see Section 18.1).

Conclusion

Relevant national and international institutions such as USDA and OIE confirm that there is no significant risk of BSE in (b)(4) Trade Secret Process - Product Specs [redacted] has stringent laws and regulations in place which regulate protection measures against BSE and BSE surveillance to assure that the country will be free of BSE also in the future. In addition the recommendations in the Guidance document:

Medical Devices Containing Materials Derived from Animal Sources (Except for In Vitro Diagnostics), November 6, 1998 have been met. Sufficient quality control measures for sourcing, processing, cleaning, storage, shipment, record keeping are in place and on site audits are conducted regularly. Therefore Geistlich believes that sourcing of bovine bone from (b)(4) Trade Secret Process for the manufacture of Geistlich Bio-Oss® and Geistlich Bio-Oss Collagen® is as safe as sourcing bovine bone from (b)(4) Trade that is currently used for the manufacture of Geistlich Bio-Oss® and Geistlich Bio-Oss Collagen® and that there is no significant risk of BSE transmission when using Geistlich Bio-Oss® or Geistlich Bio-Oss Collagen®.

8.) Device Description

8.1 Introduction

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

There have been no changes to the method of Geistlich Bio-Oss® manufacture or quality control procedures.

Geistlich Bio-Oss Collagen® is a combination of Geistlich Bio-Oss® granules with 10% collagen. The collagen is added to the product to help improve the handling of the material. The collagen is treated by mincing, drying and defatting it, (b)(4) Trade Secret Process - Product Specs as well as washing and rinsing, before being made into a slurry. The slurry is then freeze dried and cleaned. It is then combined with the Geistlich Bio-Oss® granules, made in accordance with the respective 510(k) notifications for that product into blocks of 100 mg, 250 mg and 500 mg, packaged, and sterilized with gamma irradiation.

Currently bovine bone is sourced from (b)(4) Trade which was previously cleared by the FDA under K033815. For commercial reasons Geistlich intends to obtain bovine bones from an additional geographic source - (b)(4) Trade Secret Process - Product.

There have been no changes to the method of Geistlich Bio-Oss Collagen® manufacture or quality control procedures.

(b)(4) Trade Secret Process is free of BSE and has implemented stringent laws and regulations, for BSE prevention and surveillance affecting import, traceability and feeding of cattle. The World Organization for Animal Health (OIE), an institution which represents most countries of the world including the USA, has issued a list which was last updated in May, 2012. (b)(4) Trade Secret Process is listed among the countries with *Negligible BSE* risk which represents the best possible group in terms of risk considerations of BSE (http://www.oie.int/en/animal-health-in-the-world/official-disease-status/bse/list-of-bse-risk-status/). A copy of the list is provided in Appendix 1.

USDA provides a list with countries where BSE exists (*Countries where BSE exists* or *Countries presenting an undue risk of BSE)* on its website (*Countries / Regions Affected with Bovine Spongiform Encephalopathy (BSE)*). (b)(4) Trade Secret Process is not among the countries presented on this list.[2]

After evaluation Geistlich concluded that using an alternative geographic source for the manufacture of Geistlich Bio-Oss® and Geistlich Bio-Oss Collagen® does not alter the performance characteristics and does also not raise new questions regarding safety and effectiveness of Geistlich Bio-Oss® or Geistlich Bio-Oss Collagen®.

8.2 Guidance: Medical Devices Containing Materials Derived from Animal Sources

Geistlich has considered the guidance document *Guidance for FDA Reviewers and Industry: Medical Devices Containing Materials Derived from Animal Sources (Except for In Vitro Diagnostics)*, November 6, 1998. (b)(4) Trade Secret Process - Product Specs

Trade Secret Process - Product Specs

(b)(4) Trade Secret Process - Product Specs

[2] http://www.aphis.usda.gov/import_export/animals/animal_import/animal_imports_bse.shtml

(b)(4) Trade Secret Process - Product Specs

[redacted]

(b)(4) Trade Secret Process - Product Specs

[redacted]

(b)(4) Trade Secret Process - Product Specs

[redacted]

(b)(4) Trade Secret Process - Product Specs

[redacted]

8.5 Conclusion

Relevant national and international institutions such as USDA and OIE confirm that there is no significant risk of BSE in [redacted] has stringent laws and regulations in place which regulate protection measures against BSE and BSE surveillance to assure that the country will be free of BSE also in the future. In addition the recommendations in the *Guidance document: Medical Devices Containing Materials Derived from Animal Sources (Except for In Vitro Diagnostics)*, November 6, 1998 have been met. Therefore Geistlich believes that sourcing of bovine bone from [redacted] the manufacture of Geistlich Bio-Oss® and Geistlich Bio-Oss Collagen® is as safe as sourcing bovine bone from [redacted] that is currently used for the manufacture of Geistlich Bio-Oss® and Geistlich Bio-Oss Collagen® and that there is no significant risk of BSE transmission when using Geistlich Bio-Oss® or Geistlich Bio-Oss Collagen®.

9.) Substantial Equivalence Discussion

This premarket notification is submitted to receive FDA clearance for a an alternative geographic source for the raw material bovine bone used in the production of Geistlich Bio-Oss® and Geistlich Bio-Oss Collagen®.

There have been no changes to the materials, methods of manufacture, indications for use or quality control procedures, or product specification of either Geistlich Bio-Oss® or Geistlich Bio-Oss Collagen®. The raw material bovine bone obtained from (b)(4) Trade Secret Process - Product Specs - does not represent a change in "materials" because bone will be obtained from the same species (bovine cattle) and only defined pieces of disarticulated bone will be used for manufacture of Geistlich Bio-Oss® and Geistlich Bio-Oss Collagen®.

The proposed device (Geistlich Bio-Oss®) is compared to its legally marketed predicates Geistlich Bio-Oss® (K112572, K033815, K970569) (see Table 9-1, below).

Also, the proposed device (Geistlich Bio-Oss Collagen®) is compared to its legally marketed predicates Geistlich Bio-Oss Collagen® (K112575, K112572, K092428, K974399) (see Table 9-2, below).

Table 9-1: Determination of Substantial Equivalence[3] for Geistlich Bio-Oss®

Descriptive Information	**Predicate Device: Geistlich Bio-Oss® (K112572, K033815, K970569)**	**Proposed: Geistlich Bio-Oss®**
Country of origin of the raw material bovine bone	(b)(4) Trade Secret Process - Product Specs	
Appearance	white granulate or white, porous block	white granulate or white, porous block
Moisture	less than 5% (w./w.)	less than 5% (w./w.)

[3] According to *Draft Guidance for Industry and Food and Drug Administration Staff: Evaluation Substantial Equivalence in Premarket Notifications Appendix A.*

Calcium	35%-40% (w./w.)	35%-40% (w./w.)
Phosphorous	13.5% - 18.5% (w./w.)	13.5% - 18.5% (w./w.)
(b)(4) Trade Secret Process - Product Specs [redacted]		
Heavy metals (as Pb)	less than 20 ppm	less than 20 ppm
Sterility Test	conforms to current USP	conforms to current USP
Bacterial Endotoxins	not more than 20.0 USP EU per vial	not more than 20.0 USP EU per vial
Material (Chemical) Composition	Hydroxyapatite: unchanged (see Section 15 – Bench Testing)	
Phase Purity	unchanged (see Section 15 – Bench Testing)	
Porosity	unchanged (see Section 15 – Bench Testing)	
Pore Surface Area	unchanged (see Section 15 – Bench Testing)	
Bulk Density	unchanged (see Section 15 – Bench Testing)	
Bimodal pore size distribution	unchanged (see Section 15 – Bench Testing)	
Sterilization	unchanged	
Labelling	unchanged	
Manufacturing	unchanged	
Quality Control / Quality Control Procedures	unchanged	
Intended Use	unchanged	
Physical Composition	unchanged (see above)	

Table 9-2: Determination of Substantial Equivalence[4] for Geistlich Bio-Oss Collagen®.

Descriptive Information	Predicate Device: Geistlich Bio-Oss Collagen® (K112575, K112572, K092428, K974399)	Proposed: Geistlich Bio-Oss Collagen®
Country of origin of the raw material bovine bone	(b)(4) Trade Secret Process - Product Specs [redacted]	
Appearance	white sponge-like, hard pieces of customized size	white sponge-like, hard pieces of customized size
Water	less than 8% (w./w.)	less than 8% (w./w.)
(b)(4) Trade Secret Process - Product Specs [redacted]		
Calcium	38%-42% (w./w.)	38%-42% (w./w.)
Phosphorous	12.5% - 17.5% (w./w.)	12.5% - 17.5% (w./w.)
(b)(4) Trade Secret Process - Product Specs [redacted]		
Sterility Test	conforms to current USP	conforms to current USP
Bacterial Endotoxins	not more than 20.0 USP EU per vial	not more than 20.0 USP EU per vial
Material (Chemical) Composition	Hydroxyapatite: unchanged (see Section 15 – Bench Testing)	
Phase Purity	unchanged (see Section 15 – Bench Testing)	
Porosity	unchanged (see Section 15 – Bench Testing)	

[4] According to *Draft Guidance for Industry and Food and Drug Administration Staff: Evaluation Substantial Equivalence in Premarket Notifications Appendix A.*

Pore Surface Area	unchanged (see Section 15 – Bench Testing)
Bulk Density	unchanged (see Section 15 – Bench Testing)
Bimodal pore size distribution	unchanged (see Section 15 – Bench Testing)
Sterilization	unchanged (x-ray)
Labelling	unchanged
Manufacturing	unchanged
Quality Control / Quality Control Procedures	unchanged
Intended Use	unchanged
Technological Characteristics	unchanged
Physical Composition	unchanged (see above)

10.) Proposed Labeling

The labeling for Geistlich Bio-Oss® and Geistlich Bio-Oss Collagen® will not change and will remain as cleared under 510(k) K112572. Therefore this Section does not apply.

11.) Sterilization and Shelf Life

The sterilization procedure of Geistlich Bio-Oss® and Geistlich Bio-Oss Collagen® will not change and will remain as cleared under previous 510(*k*)s.

12.) Biocompatibility

There have been no changes to the materials, methods of manufacture, or indications for use of either Geistlich Bio-Oss® or Geistlich Bio-Oss Collagen®. The raw material bovine bone obtained from (b)(4) Trade Secret Process - Product Specs [redacted] - does not represent a change in "materials" because bone will be obtained from the same species and only defined pieces of disarticulated bone will be used for manufacture of Geistlich Bio-Oss® and Geistlich Bio-Oss Collagen®.

In addition it was demonstrated by extensive laboratory testing that there is no change in material or material properties. Please refer to Section 15: Performance Testing - Bench.

Thus, the previously conducted biocompatibility testing results of Geistlich Bio-Oss® and Geistlich Bio-Oss Collagen® from (b)(4) Trade [redacted] bovine bone are fully transferable to Geistlich Bio-Oss® and Geistlich Bio-Oss Collagen® (b)(4) Trade Secret [redacted] bovine bone. No additional biocompatibility testing is deemed necessary.

13.) Software

This Section is not applicable since the devices do not contain or utilize software.

14.) Electromagnetic Compatibility and Electrical Safety

This Section is not applicable since the devices are not electromagnetic or electrical.

15.) Performance Testing – Bench

(b)(4) Trade Secret Process - Testing

[redacted]

(b)(4) Trade Secret Process - Testing

[redacted]

Conclusion:

Based on the available data it can be concluded that Geistlich Bio-Oss® manufactured from bovine bone sourced in (b)(4) Trade and bovine bone sourced in (b)(4) Trade Secret Process have identical crystal structure. Also it is confirmed that Geistlich Bio-Oss® is phase pure and 100% crystalline hydroxyapatite with no detectable impurities.

15.2 Fourier Transform Infrared Spectroscopy

(b)(4) Trade Secret Process - Testing

[redacted]

Results:

(b)(4) Trade Secret Process - Testing

[redacted]

(b)(4) Trade Secret Process - Testing

[redacted]

Conclusion: The carbonate content of Geistlich Bio Oss characteristic for the natural inorganic bone matrix could be demonstrated clearly by using the FTIR spectrum. Impurities of organic or inorganic origin could not be detected. The characteristic crystal structure, crystal size and molecule structure of Geistlich Bio-Oss® from regular manufacturing lots (b)(4) Trade Secret Process - Testing were exactly identical if compared to Geistlich Bio-Oss® manufactured from (b)(4) Trade Secret Process - Testing

15.3 HG Pressure Porosimetry

(b)(4) Trade Secret Process - Testing

Results:

(b)(4) Trade Secret Process - Testing

[redacted]

(b)(4) Trade Secret Process - Testing

[redacted]

Conclusion: Porosity, specific pore surface area, bulk density and bimodal pore size distribution were determined. All values are within a very narrow range. The data demonstrates that the micro and macro pores of Geistlich Bio-Oss® from regular manufacturing lots (b)(4) Trade Secret Process - Testing are identical to Geistlich Bio-Oss® manufactured from bovine bone (b)(4) Trade Secret Process - Testing

15.4 Overall Summary

Based on the presented data it can be concluded that the relevant physical properties of Geistlich Bio-Oss® manufactured with bovine bone [redacted] are identical to Geistlich Bio-Oss® manufactured with bovine bone [redacted] Therefore the performance characteristics of Geistlich Bio-Oss® and Geistlich Bio-Oss Collagen® are considered to remain unchanged when using the alternative geographic source, bovine bone [redacted]

References:

For further information on the investigations presented within this Section please see Appendix 4 report containing original data (Doc. No. 110413530B014A).

16.) Performance Testing – Animal

(b)(4) Trade Secret Process - Testing

[redacted]

17.) Performance Testing – Clinical

(b)(4) Trade Secret Process - Testing

[redacted]

18.) Other

18.1 Quality Controls

18.1.1 General Requirements

Geistlich Pharma AG (Geistlich) is fully compliant with QSR CFR part 820 and is certified according to ISO 9001:2008 and ISO 13845:2003. The alternative supplier of the raw material was assessed by Geistlich according to internal procedures and was integrated into the existing Quality System.

Geistlich has imposed stringent Quality Controls for sourcing, processing, cleaning, storage, shipment, record keeping and other procedures at the raw material supplier in (b)(4) Trade Secret Process - Testing [redacted] and signed Quality Agreements are in place between Geistlich and (b)(4) Trade in (on file at Geistlich). Only defined raw material (bone disks of disarticulated bones) will be used for Geistlich which will be used in the further production of Geistlich Bio-Oss® at the Geistlich facilities in Wolhusen, Switzerland.

The supplier must adhere to the signed Quality Agreement. All animals must be confirmed fit for human consumption before slaughtering in an obligatory ante-mortem examination by an official veterinarian of the (b)(4) Trade Secret Process - Testing [redacted] The Veterinarian will issue an "animal and public health certificate" which will be maintained by the supplier and will also be part of the shipment records sent to Geistlich (see example in Appendix 5).

The supplier may only produce bone disks from animals slaughtered in his own premises and according to Geistlich specifications. The slaughterhouse must have an official registration with (b)(4) Trade Secret Process - Testing [redacted] and also must be eligible for EU delivery ((b)(4) Trade Secret Process - Testing [redacted]

Storage and shipments specifications are in place and part of the Quality Agreement. After cutting, the raw material must immediately be stored in a freezing compartment at a defined temperature. The raw material is shipped together with shipping records including "animal and public health certificate", "animal status declaration" and traceability records.

18.1.2 Traceability

(b)(4) Trade Secret Process - Testing

[redacted]

18.1.3 Supplier Audits

(b)(4) Trade Secret Process - Testing

[redacted]

18.2 EDQM Certificate

EDQM (European Directorate for the Quality of Medicines & Healthcare) has granted a Certificate according to European Directive 2001/83/EC and Directive 2001/82/EC confirming compliance to the criteria of the relevant chapter of the European Pharmacopoeia (*Products with risk of transmitting agents of animal spongiform encephalopathies; 1483*) are met. The certificate was initially issued for the (b)(4) Trade Secret [redacted] and has recently been amended with the (b)(4) Trad [redacted] see the Certificate in Appendix 8.)

APPENDIX 1

World Organization for Animal Health
BSE Status of Members

World Organisation for Animal Health

Home > **Animal health in the World** > **Official disease status** > **BSE**

Bovine spongiform encephalopathy (BSE)

- List of Members' BSE risk status
- Disease distribution map
- Disease card
- Questionnaire
- Forms for annual reconfirmation

In accordance with the OIE procedure for official recognition of disease status, this page provides access to the list of OIE Member Countries officially recognised as having a negligible or controlled bovine spongiform encephalopathy (BSE) risk status by the OIE through the adoption of a Resolution by the World Assembly of Delegates (World Assembly) of the OIE at the annual General Session in May every year.

A Member Country wishing to be officially recognised as having a BSE risk status by the OIE should submit the questionnaire laid out in Chapter 1.6. of the OIE Terrestrial Animal Health Code (Terrestrial Code) and comply with all requirements specified in the Terrestrial Code for BSE. The OIE Scientific Commission for Animal Diseases (Scientific Commission) is responsible to undertake, on behalf of the World Assembly, the assessment of OIE Member Countries applications for their compliance with OIE standards. The assessment carried out by the Scientific Commission is based on the recommendations formulated by a relevant *ad hoc* Group composed of world specialists in disease control.

As the official BSE status of a country or zone is determined on the basis of an overall assessment of risk, the occurrence of a new BSE case implies a re-assessment of the official risk status only in the event of a change in the epidemiological situation indicating failure of the BSE risk mitigating measures in place.

When the Scientific Commission determines that the conditions are not met anymore to demonstrate compliance with the relevant requirements of the *Terrestrial Code*, a disease status may be suspended. The Scientific Commission may decide to reinstate the suspended status when a Member Country has submitted an application which fulfils all the requirements requested for the recovery of official disease status laid out in the relevant Chapters of the *Terrestrial Code*. The suspensions and recoveries of disease status are announced by the Director General of the OIE in consultation with the Scientific Commission and the list of these is kept up to date until adoption of a new Resolution by the World Assembly in the following May.

Member Countries enjoying a disease free status officially recognised by the OIE must submit an annual reconfirmation form by the end of November every year.

- Negligible BSE risk /
- Controlled BSE risk

Top

Bovine Spongiform Encephalopathy Status of Members

According to **RESOLUTION No. 16** (80th General Session May 2012)

- **Negligible BSE risk**

Members recognised as having a **negligible BSE risk** in accordance with Chapter 11.5 . of the *Terrestrial Code* :

Argentina	Denmark	Panama
Australia	Finland	Paraguay
Austria	Iceland	Peru

Belgium	India	Singapore
Brazil	New Zealand	Sweden
Chile	Norway	Uruguay
Colombia		

- **Controlled BSE risk**

Members recognised as having a **controlled BSE risk** in accordance with Chapter 11.5. of the *Terrestrial Code* :

Canada	Ireland	Netherlands
Chinese Taipei	Italy	Nicaragua
Croatia	Japan	Poland
Cyprus	Korea (Rep. of)	Portugal
Czech Republic	Latvia	Slovak Republic
Estonia	Lichtenstein	Slovenia
France	Lithuania	Spain
Germany	Luxembourg	Switzerland
Greece	Malta	United Kingdom
Hungary	Mexico	United States of America

Top

APPENDIX 2

(b)(4) Trade Secret Process - Product Specs

(b)(4) Trade Secret Process - Product Specs

(b)(4) Trade Secret Process - Product Specs

(b)(4) Trade Secret Process - Product Specs

(b)(4) Trade Secret Process - Product Specs

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APPENDIX 3

(b)(4) Trade Secret Process - Product Specs

[redacted]

(b)(4) Trade Secret Process - Product Specs

APPENDIX 4

(b)(4) Trade Secret Process - Testing

[redacted]

(b)(4) Trade Secret Process - Testing

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APPENDIX 5

(b)(4) Trade Secret
Process - Product Specs

(b)(4) Trade Secret Process - Product Specs

b)(4) Trade Secret Process - Product Specs

APPENDIX 6

(b)(4) Trade Secret Process - Product Specs

[redacted]

APPENDIX 7

(b)(4) Trade Secret Process -Testing Report [redacted]

(b)(4) Trade Secret Process -Testing Report

(b)(4) Trade Secret Process -Testing Report

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APPENDIX 8

(b)(4) Trade Secret
Process -Product

(b)(4) Trade Secret Process -Product specs

(b)(4) Trade Secret Process -Product specs

* * * COMMUNICATION RESULT REPORT (FEB. 21. 2013 4:22PM) * * *

FAX HEADER 1:
FAX HEADER 2:

TRANSMITTED/STORED : FEB. 21. 2013 4:19PM

FILE MODE	OPTION	ADDRESS	RESULT	PAGE
3293 MEMORY TX		RightFax	OK	3/3

REASON FOR ERROR
E-1) HANG UP OR LINE FAIL
E-2) BUSY
E-3) NO ANSWER
E-4) NO FACSIMILE CONNECTION

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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.

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Jose L. Moreno

Subject: 510(k) Number K122894/S002

To: The Record

Please list CTS decision code SE

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)

☐ Hold (Additional Information or Telephone Hold).

X Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.).

Not Substantially Equivalent (NSE) Codes

☐	NO	NSE for lack of predicate
☐	NI	NSE for new intended use
☐	NQ	NSE for new technology that raises new questions of safety and effectiveness
☐	NU	NSE for new intended use AND new technology raising new questions of safety and effectiveness
☐	NP	NSE for lack of performance data
☐	NS	NSE no response
☐	NL	NSE for lack of performance data AND no response
☐	NM	NSE pre-amendment device call for PMAs (515i)
☐	NC	NSE post-amendment device requires PMAs
☐	NH	NSE for new molecular entity requires PMA
☐	TR	NSE for transitional device

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*	x	
510(k) Summary /510(k) Statement	*Attach Summary*	x	
Truthful and Accurate Statement.	*Must be present for a Final Decision*	x	
Is the device Class III? If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		N/A
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			x
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			x
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			x
Is this device intended for pediatric use only?			N/A
Is this a prescription device? (If both prescription & OTC, check both boxes.)		x	
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			N/A
Is clinical data necessary to support the review of this 510(k)? For United States-based clinical studies **only**: Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If study was			x

conducted in the United States, and FORM FDA 3674 was not included or incomplete, then applicant must be contacted to obtain completed form.)			
Does this device include an Animal Tissue Source?		x	
All Pediatric Patients age<=21			N/A
Neonate/Newborn (Birth to 28 days)			N/A
Infant (29 days -< 2 years old)			N/A
Child (2 years -< 12 years old)			N/A
Adolescent (12 years -< 18 years old)			N/A
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			N/A
Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)			N/A
Nanotechnology			x
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	*Contact OC.*		N/A

Regulation Number **Class*** **Product Code**

___21 CFR 872.3930 _____II_____NPM_____

(*If unclassified, see 510(k) Staff)

Additional Product Codes:_____

Digital Signature Concurrence Table	
Reviewer Sign-Off	Jose L. Moreno -S 2013.02.15 11:34:03 -05'00'
Branch Chief Sign-Off	Mary S. Runner Susan Runner, DDS, MA 2013.02.15 12:44:34 -05'00'
Division Sign-Off	Kwame O. Ulmer 2013.02.15 13:42:37 -05'00'

DEPARTMENT OF HEALTH AND HUMAN SERVICES **MEMORANDUM**

Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Premarket Notification [510(k)] Review
Traditional

K122894/S002

Date: February12, 2013

To: The Record | Office: ODE

From: Jose Moreno P.h.D, Lead reviewer | Division: DAGRID

Through: Dr. Susan Runner, Branch Chief | Branch: DDB

510(k) Holder: Geistlich Pharma AG

Device Name: Getistlich Bio-Oss: Natural Bone Grafting Material

Getistlich Bio-Oss Collagen: Natural Bone Grafting Material plus Collagen

Contact: Daniel A. Kracov, Arnold & Porter LLP

Phone: 202-942-5120

Fax: 202-942-5999

Email: Daniel.Kracov@aporter.com

I. Purpose and Submission Summary

Geistlich Pharma AG, of Wolhusen, Switzerland, has submitted a Premarket Notification (510(k)) to provide for an alternative geographic source for the raw material bovine bone used in the production of the Geistlich Bio-Oss® and Geistlich Bio-Oss Collagen® family of products. (b)(4) Trade Secret Process -Product specs [redacted]

(b)(4) Trade Secret Process -Product specs

[redacted]

II. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription)	X		
(Indicate if: OTC)		X	
Truthful and Accuracy Statement	X		
Standards Form			X

The sponsor has submitted two 510 (k) Summaries, one for Geistlich Bio-Oss and one for Geistlich Bio-Oss Collagen.

			YES	NO	N/A
Required Elements for 510(k) Summary (21 CFR 807.92)					
	Clearly labeled "510(k) Summary"		X		
	Submitter' s name, address, phone #, a contact person		X		
	Date the summary was prepared		X		
	The name of the device/trade name/common name/classification name		X		
	An identification of the legally marketed Predicate		X		
	Description of the subject device		X		
	Statement of intended use(identical to indications for use)_		X		
Technological		if same, a summary of comparison of technological characters	X		
Technological		If different, a summary of how do they compare to the Predicate			X
Performance Data		Brief discussion of non-clinical data submitted, referenced, or relied on	X		
Performance Data		Brief discussion of clinical data submitted, referenced, or relied on, including: ▪ Description upon whom the device was tested, ▪ Data obtained from the tests and especially: ▪ Adverse events and complications ▪ Other information for SE determination			X
Performance Data		Conclusion that data demonstrate SE	X		
Required Elements for 510(k) Statement (21 CFR 807.93)					

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		YES	NO	N/A
	Signed verbatim statement			X

(b)(4) Trade Secret Process -Product specs

[redacted]

(b)(4) Trade Secret Process -Product specs

[redacted]

(b)(4) Trade Secret Process -Product specs

[redacted]

(b)(4) Trade Secret Process -Product specs

[redacted]

(b)(4) Trade Secret Process -Product specs

[redacted]

(b)(4) Trade Secret Process -Product specs

[redacted]

(b)(4) Trade Secret Process -Product specs

[redacted]

(b)(4) Trade Secret Process -Product specs

[redacted]

(b)(4) Trade Secret Process -Product specs

[redacted]

(b)(4) Trade Secret Process -Product specs

[redacted]

(b)(4) Trade Secret Process -Product specs

[redacted]

21

(b)(4) Trade Secret Process -Product specs

[redacted]

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.)

(b)(4) Trade Secret Process -Product specs

[redacted] (b)(4) [redacted]. The device is available as part of two convenient kits and in 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
- 1block 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

(b)(4) Trade Secret Process -Product specs

[redacted]

(b)(4) Trade Secret Process -Product specs

[redacted]

(b)(4) Trade Secret Process -Product specs

[redacted]

(b)(4) Trade Secret Process -Product specs

[redacted]

(b)(4) Trade Secret Process -Product specs

[redacted]

VII. Biocompatibility

(b)(4) Trade Secret Process -Product specs

[redacted]

VIII. Software

N/A

IX. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

N/A

X. Performance Testing – Bench

(b)(4) Trade Secret Process -Product specs

[redacted]

(b)(4) Trade Secret Process -Testing

[redacted]

(b)(4) Trade Secret Process -Testing

[redacted]

(b)(4) Trade Secret Process -Testing

[redacted]

XI. Performance Testing – Animal

(b)(4) Trade Secret Process -Testing

[redacted]

(b)(4) Trade Secret Process -Testing

[redacted]

XII. Performance Testing – Clinical

(b)(4) Trade Secret Process -Testing

[redacted]

XIII. Predicate Device Comparison

(b) (4)

[redacted]

Descriptive Information Predicate Device:	Predicate Device: Geistlich Bio-Oss® (K112572, K033815, K970569)	Proposed: Geistlich Bio-Oss
Country of origin of the raw material bovine bone	(b) (4) [redacted]	
Appearance	white granulate or white, porous block	white granulate or white, porous block
Moisture	less than 5% (w./w.)	less than 5% (w./w.)
Calcium	35%-40% (w./w.)	35%-40% (w./w.)
(b) (4) [redacted]		
Heavy metals (as Pb)	less than 20 ppm	less than 20 ppm
Sterility Test	conforms to current USP	conforms to current USP
Bacterial Endotoxins	not more than 20.0 USP EU per vial	not more than 20.0 USP
Material (Chemical) Composition	Hydroxyapatite: unchanged (see Section 15 – Bench Testing)	

Phase Purity	unchanged (see Section 15- Bench Testing) .
Porosity	unchanged (see Section 15- Bench Testing) .
Pore Surface Area	unchanged (see Section 15- Bench Testing) .
Bulk Density	unchanged (see Section 15- Bench Testing) .
Bimodal pore size distribution	unchanged (see Section 15- Bench Testing) .
Sterilization	Unchanged
Labeling	Unchanged
Manufacturing unchanged	Unchanged
Quality Control/ Quality Control Procedures	Unchanged
Intended Use	Unchanged
Physical Composition	Unchanged

(b)(4) Trade Secret Process -Product Specs

Descriptive Information Predicate Device:	**Predicate Device: Geistlich Bio-Oss Collagen® (K112575, K112572, K092428, K974399)**	**Proposed: Geistlich Bio-Oss Collagen®**
Country of origin of the raw material bovine bone	(b)(4) Trade Secret Process -Product Specs	
Appearance	white granulate or white, porous block	white sponge-like, hard pieces of customized size
Water	less than 8% (w./w.)	less than 8% (w./w.)
Residue on ignition		
Calcium	38%-42% (w./w.)	38%-42% (w./w.)
Phosphorous	12.5%- 17.5% (w./w.)	12.5%- 17.5% (w./w.)
Nitrogen	(b)(4) Trade Secret Process -Product Specs	
4-Hydroxiproline		
Sterility Test	conforms to current USP	conforms to current USP
Bacterial Endotoxins	not more than 20.0 USP EU per vial	not more than 20.0 USP EU per vial
Material (Chemical) Composition	Hydroxyapatite: unchanged (see Section 15 – Bench Testing)	
Phase Purity	unchanged (see Section 15- Bench Testing) .	
Porosity	unchanged (see Section 15- Bench Testing) .	
Pore Surface Area	unchanged (see Section 15- Bench Testing) .	

Bulk Density	unchanged (see Section 15- Bench Testing) .
Bimodal pore size distribution	unchanged (see Section 15- Bench Testing) .
Sterilization	unchanged (x-ray)
Labeling	Unchanged
Manufacturing unchanged	Unchanged
Quality Control/ Quality Control Procedures	Unchanged
Intended Use	Unchanged
Technological Characteristics	Unchanged
Physical Composition	Unchanged

(b)(4) Trade Secret Process -Product Specs

[redacted]

XIV. Substantial Equivalence Discussion

	Yes	No	
1. Same Indication Statement?	x		If **YES** = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NSE**
3. Same Technological Characteristics?	x		If **YES** = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?			If **YES** = Go To 6
5. Descriptive Characteristics Precise Enough?		x	If **NO** = Go To 8 If **YES** = Stop **SE**
6. New Types Of Safety Or Effectiveness Questions?			If **YES** = Stop **NSE**
7. Accepted Scientific Methods Exist?			If **NO** = Stop **NSE**
8. Performance Data Available?		x	If **NO** = Request Data
9. Data Demonstrate Equivalence?	x		Final Decision: **SE**

Note: See
http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kPr

(b)(4) Trade Secret Process -Product Specs

[redacted]

(b)(4) Trade Secret Process -Product Specs

[redacted]

(b)(4) Trade Secret Process -Product Specs

[redacted]

(b)(4) Trade Secret Process -Product Specs

[redacted]

(b)(4) Trade Secret Process -Product Specs

[redacted]

(b)(4) Trade Secret Process -Product Specs

[redacted]

Performance Testing – Bench

(b)(4) Trade Secret Process -Product Specs

[redacted]

(b)(4) Trade Secret Process -Product Specs

[redacted]

XVI. Contact History

(b)(4) Trade Secret Process -Product Specs

[redacted]

XVII. **Recommendation:** I recommend that the current submission is found **Substantially Equivalent.**

Regulation Number: 21 CFR 872.3930
Regulation Name: Bone grafting material
Regulatory Class: NPM
Product Code: **Class II**

Digital Signature Concurrence Table	
Reviewer Sign-Off Jose L. Moreno Ph.D. Scientific Reviewer	Jose L. Moreno -S 2013.02.15 07:11:08 -05'00' Jose L. Moreno -S 2013.02.15 09:54:52 -05'00'
Branch Chief Sign-Off M. Susan Runner, D.D.S., M.A. Branch Chief Dental Devices	Susan Runner, DDS, MA Mary S. Runner 2013.02.15 09:27:01 -05'00'
Division Sign-Off	

Revised 510(K) Summaries

510(k) Summary

GEISTLICH BIO-OSS®

SPONSOR

Geistlich Pharma AG
Bahnhofstrasse 40
CH-6110 Wolhusen
Switzerland

Contact Person:	Daniel Kracov, Arnold & Porter, LLP Counsel to Geistlich Pharma AG
E-mail:	Daniel.Kracov@aporter.com
Phone:	202-942-5120
Fax:	202-942-5999
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
Bahnhofstrasse 40
CH-6110 Wolhusen
Switzerland

Contact Person:	Daniel Kracov, Arnold & Porter, LLP Counsel to Geistlich Pharma AG
E-mail:	Daniel.Kracov@aporter.com
Phone:	202-942-5120
Fax:	202-942-5999
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
- 1block 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
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Jose L. Moreno

Subject: 510(k) Number K123894

To: The Record

Please list CTS decision code TH

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)

☒ Hold (Additional Information or Telephone Hold).

☐ Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.).

Not Substantially Equivalent (NSE) Codes

☐	NO	NSE for lack of predicate
☐	NI	NSE for new intended use
☐	NQ	NSE for new technology that raises new questions of safety and effectiveness
☐	NU	NSE for new intended use AND new technology raising new questions of safety and effectiveness
☐	NP	NSE for lack of performance data
☐	NS	NSE no response
☐	NL	NSE for lack of performance data AND no response
☐	NM	NSE pre-amendment device call for PMAs (515i)
☐	NC	NSE post-amendment device requires PMAs
☐	NH	NSE for new molecular entity requires PMA
☐	TR	NSE for transitional device

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*		
510(k) Summary /510(k) Statement	*Attach Summary*		
Truthful and Accurate Statement.	*Must be present for a Final Decision*		
Is the device Class III?			
If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			
Is this device intended for pediatric use only?			
Is this a prescription device? (If both prescription & OTC, check both boxes.)			
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			
Is clinical data necessary to support the review of this 510(k)?			
For United States-based clinical studies **only**: Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If study was			

conducted in the United States, and FORM FDA 3674 was not included or incomplete, then applicant must be contacted to obtain completed form.)

Does this device include an Animal Tissue Source?

All Pediatric Patients age<=21

Neonate/Newborn (Birth to 28 days)

Infant (29 days -< 2 years old)

Child (2 years -< 12 years old)

Adolescent (12 years -< 18 years old)

Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)

Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)

Nanotechnology

Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html) *Contact OC.*

Regulation Number **Class*** **Product Code**

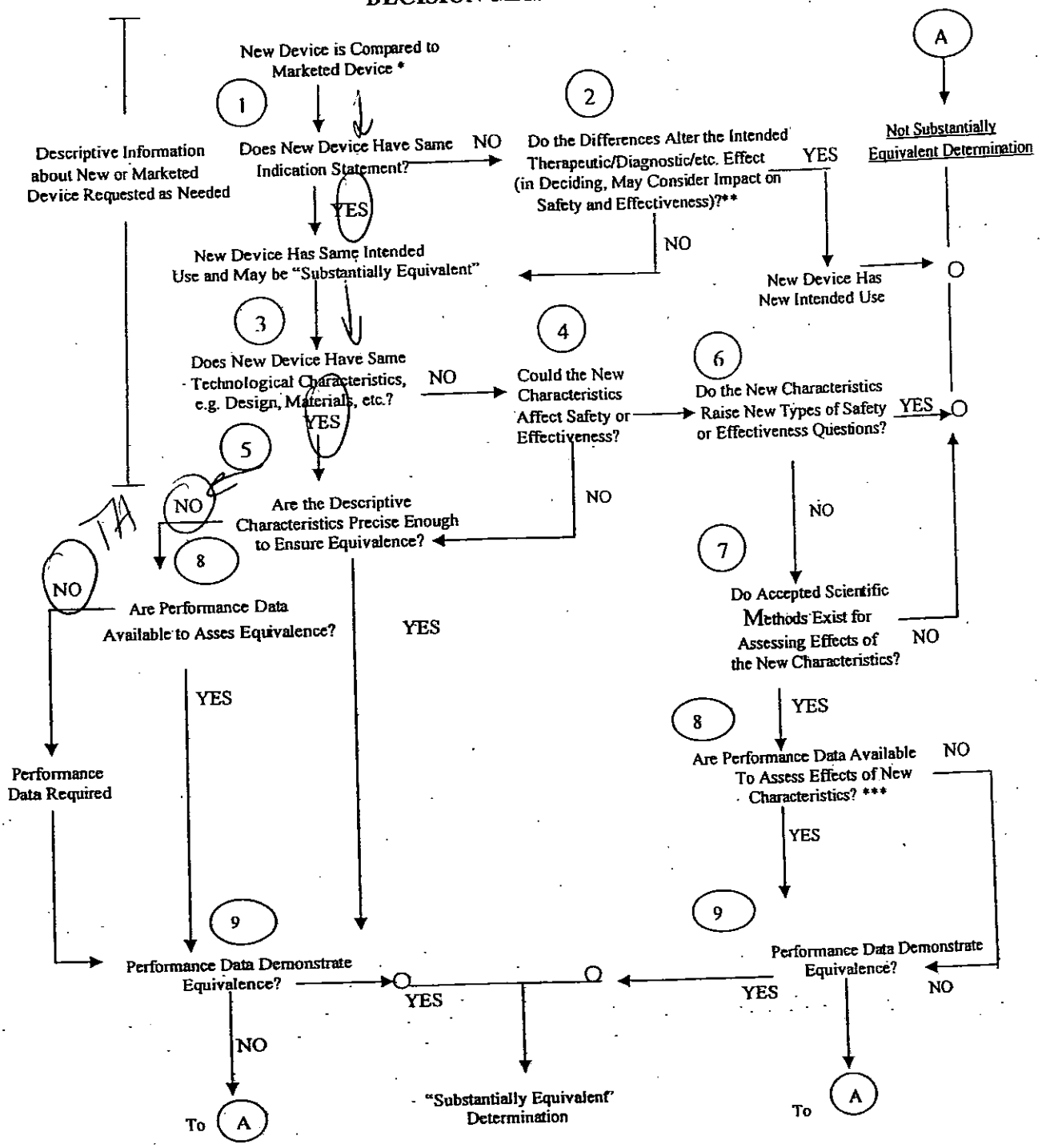
(*If unclassified, see 510(k) Staff)

Additional Product Codes:

Review: B Betz DDS for Dr. S. Runner / DEDB 11-21-12
(Branch Chief) (Branch Code) (Date)

Final Review:
(Division Director) (Date)

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

DEPARTMENT OF HEALTH AND HUMAN SERVICES **MEMORANDUM**

Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Premarket Notification [510(k)] Review
Traditional

K122894

Date: November 21, 2012

To: The Record — Office: ODE

From: Jose Moreno P.h.D, Lead reviewer 11/21/12 — Division: DAGRID

Through: Dr. Susan Runner, Branch Chief — Branch: DDB

510(k) Holder: Geistlich Pharma AG

Device Name: Geistlich Bio-Oss: Natural Bone Grafting Material
Geistlich Bio-Oss Collagen: Natural Bone Grafting Material plus Collagen

Contact: Daniel A. Kracov, Arnold & Porter LLP

Phone: 202-942-5120

Fax: 202-942-5999

Email: Daniel.Kracov@aporter.com

I. Purpose and Submission Summary

Geistlich Pharma AG, of Wolhusen, Switzerland, has submitted a Premarket Notification (510(k)) to provide for an alternative geographic source for the raw material bovine bone used in the production of the Geistlich Bio-Oss® and Geistlich Bio-Oss Collagen® family of products. (b)(4) Trade Secret Process -Product Specs [redacted]

(b)(4) Trade Secret Process -Product Specs

[redacted]

II. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription)	X		
(Indicate if: OTC)		X	
Truthful and Accuracy Statement	X		
Standards Form			X

(b)(4) Trade Secret Process -Product Specs

[redacted]

			YES	NO	N/A
Required Elements for 510(k) Summary (21 CFR 807.92)					
	Clearly labeled "510(k) Summary"		X		
	Submitter' s name, address, phone #, a contact person		X		
	Date the summary was prepared		X		
	The name of the device/trade name/common name/classification name		X		
	An identification of the legally marketed Predicate		X		
	Description of the subject device		X		
	Statement of intended use(identical to indications for use)_		X		
	Technological	if same, a summary of comparison of technological characters	X		
		If different, a summary of how do they compare to the Predicate			X
	Performance Data	Brief discussion of non-clinical data submitted, referenced, or relied on	X		
		Brief discussion of clinical data submitted, referenced, or relied on, including: ▪ Description upon whom the device was tested, ▪ Data obtained from the tests and especially: ▪ Adverse events and complications ▪ Other information for SE determination			X
		Conclusion that data demonstrate SE	X		
Required Elements for 510(k) Statement (21 CFR 807.93)					
	Signed verbatim statement				X

(b)(4) Trade Secret Process -Product Specs

[redacted]

(b)(4) Trade Secret Process -Product Specs

[redacted]

(b)(4) Trade Secret Process -Product Specs

[redacted]

(b)(4) Trade Secret Process -Product Specs

[redacted]

III. Device Description

	Yes	No	N/
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?	X		
Does the device design use software?		X	
Is the device sterile?	X		
Is the device reusable (not reprocessed single use) and are "cleaning" instructions included for the end user?			X

(b)(4) Trade Secret Process -Product Specs

[redacted]

60

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.)

(b)(4) Trade Secret Process -Product Specs

[redacted]

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
- 1block 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

(b)(4) Trade Secret Process -Product Specs

[redacted]

(b)(4) Trade Secret Process -Product Specs

[redacted]

(b)(4) Trade Secret Process -Product Specs

[redacted]

IV. Indications for Use

(b)(4) Trade Secret Process -Product Specs

[redacted]

V. Labeling

(b)(4) Trade Secret Process -Product Specs

[redacted]

VI. Sterilization/Shelf Life/Reuse

(b)(4) Trade Secret Process -Product Specs

[redacted]

(b)(4) Trade Secret Process -Product Specs

[redacted]

VII. Biocompatibility

(b)(4) Trade Secret Process -Product Specs

[redacted]

VIII. Software

N/A

IX. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

N/A

X. Performance Testing – Bench

(b)(4) Trade Secret Process -Product Specs

[redacted]

(b)(4) Trade Secret Process -Product Specs

[redacted]

XI. Performance Testing – Animal

(b)(4) Trade Secret Process -Product Specs

[redacted]

(b)(4) Trade Secret Process -Product Specs

[redacted]

II. Performance Testing – Clinical

(b)(4) Trade Secret Process -Product Specs

[redacted]

III. Predicate Device Comparison

(b)(4) Trade Secret Process -Product Specs

[redacted]

Descriptive Information Predicate Device:	Predicate Device: Geistlich Bio-Oss® (K112572, K033815, K970569)	Proposed: Geistlich Bio-Oss
Country of origin of the raw material bovine bone	(b)(4) Trade Secret Process -Product Specs [redacted]	
Appearance	white granulate or white, porous block	white granulate or white, porous block
Moisture	less than 5% (w./w.)	less than 5% (w./w.)
Calcium	35%-40% (w./w.)	35%-40% (w./w.)
Phosphorous	13.5% - 18.5% (w./w.)	13.5% - 18.5% (w./w.)
(b)(4) Trade Secret Process -Product Specs [redacted]		
Heavy metals (as Pb)	less than 20 ppm	less than 20 ppm
Sterility Test	conforms to current USP	conforms to current USP
Bacterial Endotoxins	not more than 20.0 USP EU per vial	not more than 20.0 USP
Material (Chemical) Composition	Hydroxyapatite: unchanged (see Section 15 – Bench Testing)	
Phase Purity	unchanged (see Section 15- Bench Testing) .	
Porosity	unchanged (see Section 15- Bench Testing) .	

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Pore Surface Area	unchanged (see Section 15- Bench Testing) .
Bulk Density	unchanged (see Section 15- Bench Testing) .
Bimodal pore size distribution	unchanged (see Section 15- Bench Testing) .
Sterilization	Unchanged
Labeling	Unchanged
Manufacturing unchanged	Unchanged
Quality Control/ Quality Control Procedures	Unchanged
Intended Use	Unchanged
Physical Composition	Unchanged

The sponsor has identified Geistlich Bio-Oss Collagen cleared under K112575, K112572, K092428 and K974399 as the legally marketed predicate device for the Geistlich Bio-Oss Collagen device in the current submission. The sponsor has provided the following comparison table:

Descriptive Information Predicate Device:	**Predicate Device: Geistlich Bio-Oss Collagen® (K112575, K112572, K092428, K974399)**	**Proposed: Geistlich Bio-Oss Collagen®**
Country of origin of the raw material bovine bone	(b)(4) Trade Secret Process -Product Specs [redacted]	
Appearance	white granulate or white, porous block	white sponge-like, hard pieces of customized size
Water	less than 8% (w./w.)	less than 8% (w./w.)
(b)(4) Trade Secret [redacted]	[redacted]	[redacted]
Calcium	38%-42% (w./w.)	38%-42% (w./w.)
Phosphorous	12.5%- 17.5% (w./w.)	12.5%- 17.5% (w./w.)
(b)(4) Trade Secret Process -Product Specs [redacted]		
Sterility Test	conforms to current USP	conforms to current USP
Bacterial Endotoxins	not more than 20.0 USP EU per vial	not more than 20.0 USP EU per vial
Material (Chemical) Composition	Hydroxyapatite: unchanged (see Section 15 – Bench Testing)	
Phase Purity	unchanged (see Section 15- Bench Testing) .	
Porosity	unchanged (see Section 15- Bench Testing) .	
Pore Surface Area	unchanged (see Section 15- Bench Testing) .	
Bulk Density	unchanged (see Section 15- Bench Testing) .	
Bimodal pore size	unchanged (see Section 15- Bench Testing) .	

distribution	
Sterilization	unchanged (x-ray)
Labeling	Unchanged
Manufacturing unchanged	Unchanged
Quality Control/ Quality Control Procedures	Unchanged
Intended Use	Unchanged
Technological Characteristics	Unchanged
Physical Composition	Unchanged

(b)(4) Trade Secret Process -Product Specs

[redacted]

IV. Substantial Equivalence Discussion

	Yes	No	
1. Same Indication Statement?	x		If **YES** = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NSE**
3. Same Technological Characteristics?	x		If **YES** = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?			If **YES** = Go To 6
5. Descriptive Characteristics Precise Enough?		x	If **NO** = Go To 8 If **YES** = Stop **SE**
6. New Types Of Safety Or Effectiveness Questions?			If **YES** = Stop **NSE**
7. Accepted Scientific Methods Exist?			If **NO** = Stop **NSE**
8. Performance Data Available?		x	If **NO** = Request Data
9. Data Demonstrate Equivalence?			Final Decision:

Note: See http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4148/FLOWCHART%20DECISION%20TREE%20.DOC for Flowchart to assist in decision-making process. Please complete the following table and answer the

(b)(4) Trade Secret Process -Product Specs

[redacted]

(b)(4) Trade Secret Process -Product Specs

[redacted]

(b)(4) Trade Secret Process -Product Specs

[redacted]

Device Description

(b)(4) Trade Secret Process -Product Specs

[redacted]

Shelf Life

(b)(4) Trade Secret Process -Product Specs

[redacted]

Performance Testing – Bench

(b)(4) Trade Secret Process -Product Specs

[redacted]

(b)(4) Trade Secret Process -Product Specs

[redacted]

VI. **Contact History**

(b)(4) Tr [redacted]

VII. (b)(4) Trade Secret Process -Product Specs [redacted]

[redacted]

Digital Signature Concurrence Table	
Reviewer Sign-Off Jose L. Moreno Ph.D. Scientific Reviewer	Jose L. Moreno -S 2012.11.21 13:28:45 -05'00'
Branch Chief Sign-Off M. Susan Runner, D.D.S., M.A. Branch Chief Dental Devices	Robert S. Betz 2012.11.21 14:27:51 -05'00'
Division Sign-Off	

Moreno, Jose L.

om:	Moreno, Jose L.
sent:	Wednesday, November 21, 2012 2:36 PM
To:	'Daniel.Kracov@aporter.com'
Cc:	Runner, Susan; Betz, Bob
Subject:	K122894
Attachments:	AI K122894.docx
Sensitivity:	Confidential

Premarket Notification [510(k)] Review
Traditional

K122894

Date: November 21, 2012
To: The Record — Office: ODE
From: Jose Moreno Ph.D., Lead reviewer — Division: DAGRID
Through: Dr. Susan Runner, Branch Chief — Branch: DDB
510(k) Holder: Geistlich Pharma AG
Device Name: Geistlich Bio-Oss: Natural Bone Grafting Material
Geistlich Bio-Oss Collagen: Natural Bone Grafting Material plus Collagen
Contact: Daniel A. Kracov, Arnold & Porter LLP
Phone: 202-942-5120
Fax: 202-942-5999
Email: Daniel.Kracov@aporter.com

(b)(4) Trade Secret Process -Product Specs

[redacted]

Performance Testing – Bench

(b)(4) Trade Secret Process -Product Specs

[redacted]

(b)(4) Trade Secret Process -Product Specs

[redacted]

(b)(4) Trade Secret Process -Product Specs

[redacted]

Device Description

(b)(4) Trade Secret Process -Product Specs

[redacted]

Shelf Life

(b)(4) Trade Secret Process -Product Specs

[redacted]

The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to the Document Mail Center (DMC) at the following address:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
10903 New Hampshire Avenue
cument Mail Center - WO66-0609
Silver Spring, MD 20993-0002

(b)(4) Trade Secret Process -Product Specs

[redacted]

Regards,

Jose L. Moreno Ph.D.
Staff Fellow
Dental Devices Branch
Division of Anesthesiology, General Hospital, Respiratory, Infection Control and Dental Devices
Office of Device Evaluation, Center for Devices and Radiologic Health
10903 New Hampshire Ave Bldg. 66 Room 1527
Silver Spring, MD 20993-0002
Phone 301-796-6952
Fax 301-847-8109
Jose.Moreno2@fda.hhs.gov

Moreno, Jose L.

ım:	Microsoft Outlook
ıo:	'Daniel.Kracov@aporter.com'
Sent:	Wednesday, November 21, 2012 2:36 PM
Subject:	Relayed: K122894

Delivery to these recipients or groups is complete, but no delivery notification was sent by the destination server:

'Daniel.Kracov@aporter.com' (Daniel.Kracov@aporter.com)

Subject: K122894

Moreno, Jose L.

ım:	Kracov, Daniel A. <Daniel.Kracov@APORTER.COM>
ɔent:	Wednesday, November 21, 2012 2:38 PM
To:	Moreno, Jose L.
Subject:	Read: K122894
Attachments:	Read: K122894

(b)(4) Trade Secret Process -Product Specs

[redacted]

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K 122894/S1 V1

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

January 04, 2013

GEISTLICH PHARMA AG
C/O ARNOLD & PORTER LLP
555 TWELFTH STREET, NW
WASHINGTON, DISTRICT OF COLUMBIA 20004-1206
ATTN: DANIEL A. KRACOV

510k Number: K122894

Product: GEISTLICH BIO-OSS, GEISTLICH B

On Hold As of 1/2/2013

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm.

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceProvisionsofFDAModernizationAct/ucm136685.htm.

In accordance with 21 CFR 807.87(l), FDA may consider a 510(k) to be withdrawn if the submitter fails to provide additional information within 30 days of an Additional Information (AI) request. FDA generally permits submitters additional time to respond to such requests. FDA intends to automatically grant a maximum of 180 calendar days from the date of the AI request, even if the submitter has not requested an extension. Therefore, submitters are no longer required to submit written requests for extension. However, submitters should be aware that FDA intends to issue a notice of withdrawal under 21 CFR 807.87(l) if FDA does not receive, in a submission to the appropriate Document Control Center, a complete response to all of the deficiencies in the AI request within 180 calendar days of the date that FDA issued that AI request. In this instance, pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

For further information regarding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee Amendments of 2012 (MDUFA III), to the Federal Food, Drug, and Cosmetic Act, you may refer to our guidance document entitled "Guidance for Industry and Food and Drug Administration Staff - FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Goals". You may review this document at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089735.htm>.

Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely yours,

Marjorie Shulman
Director, 510(k) Program
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

Nichols, Karl *

From: Napperli, Jesse *
Sent: Friday, January 04, 2013 8:50 AM
To: Nichols, Karl *
Subject: FW: K122894 HOLD

From: Napperli, Jesse *
Sent: Friday, January 04, 2013 8:48 AM
To: 'DANIEL.KRACOV@APORTER.COM'; DCCLetters
Subject: K122894 HOLD

k122894 HOLD 1-2.rtf

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Jose L. Moreno

Subject: 510(k) Number K122894/S1

To: The Record

Please list CTS decision code TH

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207'202%2007.doc)

☒ Hold (Additional Information or Telephone Hold).

☐ Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.).

Not Substantially Equivalent (NSE) Codes

☐	NO	NSE for lack of predicate
☐	NI	NSE for new intended use
☐	NQ	NSE for new technology that raises new questions of safety and effectiveness
☐	NU	NSE for new intended use AND new technology raising new questions of safety and effectiveness
☐	NP	NSE for lack of performance data
☐	NS	NSE no response
☐	NL	NSE for lack of performance data AND no response
☐	NM	NSE pre-amendment device call for PMAs (515i)
☐	NC	NSE post-amendment device requires PMAs
☐	NH	NSE for new molecular entity requires PMA
☐	TR	NSE for transitional device

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*		
510(k) Summary /510(k) Statement	*Attach Summary*		
Truthful and Accurate Statement.	*Must be present for a Final Decision*		
Is the device Class III?			
If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			
Is this device intended for pediatric use only?			
Is this a prescription device? (If both prescription & OTC, check both boxes.)			
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			
Is clinical data necessary to support the review of this 510(k)?			
For United States-based clinical studies **only**: Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If study was			

conducted in the United States, and FORM FDA 3674 was not included or incomplete, then applicant must be contacted to obtain completed form.)

Does this device include an Animal Tissue Source?

All Pediatric Patients age<=21

Neonate/Newborn (Birth to 28 days)

Infant (29 days -< 2 years old)

Child (2 years -< 12 years old)

Adolescent (12 years -< 18 years old)

Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)

Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)

Nanotechnology

Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html) *Contact OC.*

Regulation Number	Class*	Product Code

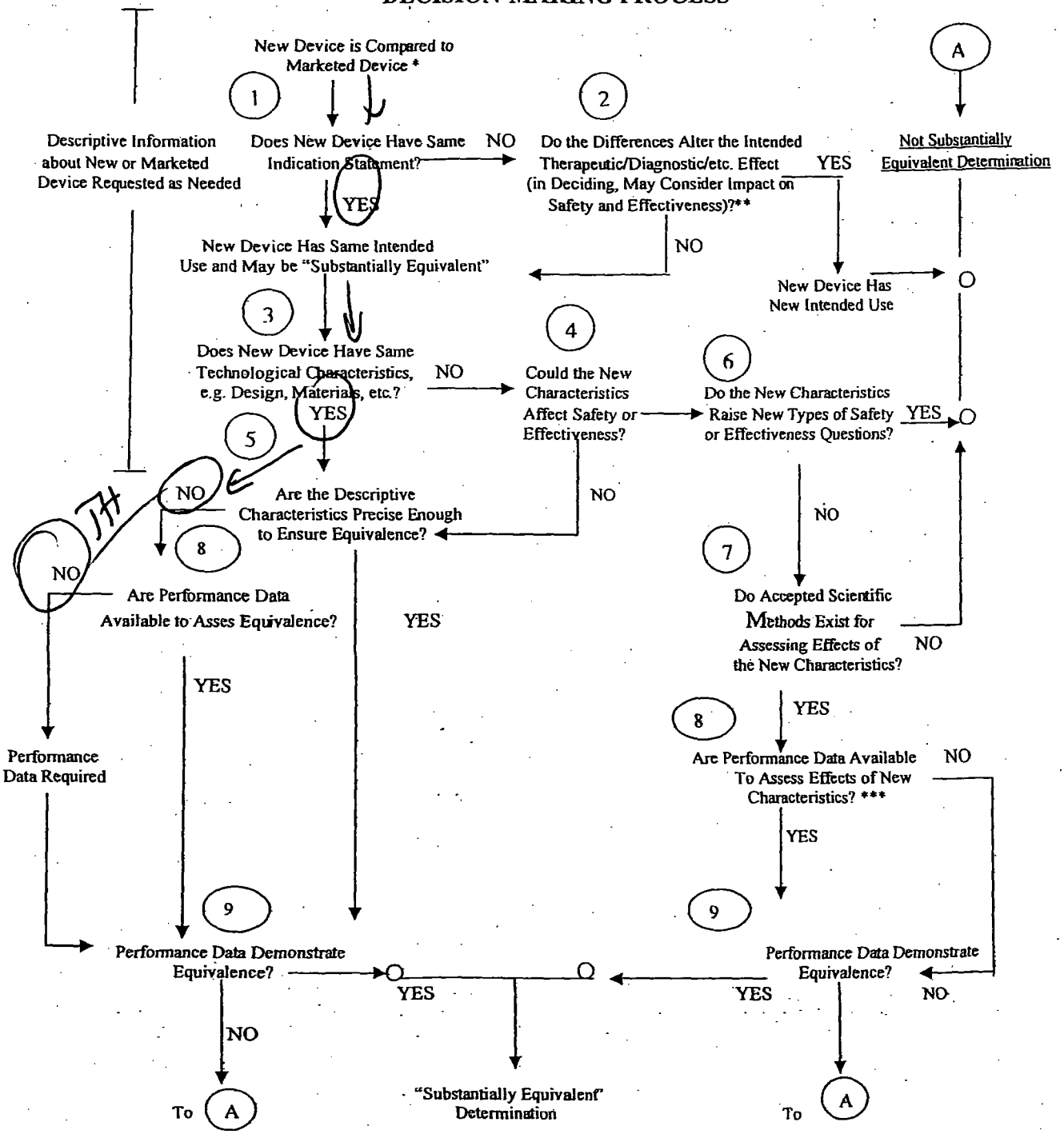
(*If unclassified, see 510(k) Staff)

Additional Product Codes:

Review: Susan Runner (Branch Chief) DSA (Branch Code) 1/2/13 (Date)

Final Review: Susan Runner (Division Director) 1/2/13 (Date)

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

December 20, 2012

GEISTLICH PHARMA AG
C/O ARNOLD & PORTER LLP
555 TWELFTH STREET, NW
WASHINGTON, DISTRICT OF COLUMBIA 20004-1206
ATTN: DANIEL A. KRACOV

510k Number: K122894

Product: GEISTLICH BIO-OSS, GEISTLICH B

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Pleaseremember that all correspondence concerning your submission MUST be sent to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely,

510(k) Staff

DEPARTMENT OF HEALTH AND HUMAN SERVICES **MEMORANDUM**

Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Premarket Notification [510(k)] Review
Traditional

K122894/S001

Date: January 2nd, 2013

To: The Record | Office: ODE

From: Jose Moreno P.h.D, Lead reviewer | Division: DAGRID

Through: Dr. Susan Runner, Branch Chief | Branch: DDB

510(k) Holder: Geistlich Pharma AG

Device Name: Getistlich Bio-Oss: Natural Bone Grafting Material

Getistlich Bio-Oss Collagen: Natural Bone Grafting Material plus Collagen

Contact: Daniel A. Kracov, Arnold & Porter LLP

Phone: 202-942-5120

Fax: 202-942-5999

Email: Daniel.Kracov@aporter.com

I. Purpose and Submission Summary

Geistlich Pharma AG, of Wolhusen, Switzerland, has submitted a Premarket Notification (510(k)) to provide for an alternative geographic source for the raw material bovine bone used in the production of the Geistlich Bio-Oss® and Geistlich Bio-Oss Collagen® family of products. (b)(4) Trade Secret Process -Product Specs [redacted]

(b)(4) Trade Secret Process -Product Specs

[redacted]

II. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription)	X		
(Indicate if: OTC)		X	
Truthful and Accuracy Statement	X		
Standards Form			X

(b)(4) Trade Secret Process -Product Specs

[redacted]

			YES	NO	N/A
Required Elements for 510(k) Summary (21 CFR 807.92)					
	Clearly labeled "510(k) Summary"		X		
	Submitter' s name, address, phone #, a contact person		X		
	Date the summary was prepared		X		
	The name of the device/trade name/common name/classification name		X		
	An identification of the legally marketed Predicate		X		
	Description of the subject device		X		
	Statement of intended use(identical to indications for use)		X		
Technological		if same, a summary of comparison of technological characters	X		
Technological		If different, a summary of how do they compare to the Predicate			X
Performance Data		Brief discussion of non-clinical data submitted, referenced, or relied on	X		
Performance Data		Brief discussion of clinical data submitted, referenced, or relied on, including: ▪ Description upon whom the device was tested, ▪ Data obtained from the tests and especially: ▪ Adverse events and complications ▪ Other information for SE determination			X
Performance Data		Conclusion that data demonstrate SE	X		
Required Elements for 510(k) Statement (21 CFR 807.93)					

		YES	NO	N/A
	Signed verbatim statement			X

(b)(4) Trade Secret Process -Product Specs

[redacted]

(b)(4) Trade Secret Process -Product Specs

[redacted]

(b)(4) Trade Secret Process -Product Specs

[redacted]

(b)(4) Trade Secret Process -Product Specs

[redacted]

(b)(4) Trade Secret Process -Product Specs

[redacted]

(b)(4) Trade Secret Process -Product Specs

[redacted]

(b)(4) Trade Secret Process -Product Specs

[redacted]

(b)(4) Trade Secret Process -Product Specs

[redacted]

(b)(4) Trade Secret Process -Product Specs

[redacted]

III. Device Description

	Yes	No	N/
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?	X		
Does the device design use software?		X	

	Yes	No	N/
Is the device sterile?	X		
Is the device reusable (not reprocessed single use) and are "cleaning" instructions included for the end user?			X

(b)(4) Trade Secret Process -Product Specs

[redacted]

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
- 1block 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

(b)(4) Trade Secret Process -Product Specs

[redacted]

(b)(4) Trade Secret Process -Product Specs

[redacted]

(b)(4) Trade Secret Process -Product Specs

[redacted]

(b)(4) Trade Secret Process -Product Specs [redacted].

IV. Indications for Use

(b)(4) Trade Secret Process -Product Specs [redacted]

V. Labeling

(b)(4) Trade Secret Process -Product Specs [redacted]

VI. Sterilization/Shelf Life/Reuse

(b)(4) Trade Secret Process -Product Specs

[redacted]

VII. Biocompatibility

(b)(4) Trade Secret Process -Product Specs

[redacted]

VIII. Software

N/A

IX. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

N/A

X. Performance Testing – Bench

(b)(4) Trade Secret Process -Product Specs

[redacted]

(b)(4) Trade Secret Process -Product Specs

[redacted]

(b)(4) Trade Secret Process -Product Specs

[redacted]

(b)(4) Trade Secret Process -Product Specs

[redacted]

XI. Performance Testing – Animal

(b)(4) Trade Secret Process -Product Specs

[redacted]

XII. Performance Testing – Clinical

(b)(4) Trade Secret Process -Product Specs

[redacted]

XIII. Predicate Device Comparison

(b)(4) Trade Secret Process -Product Specs

[redacted]

Descriptive Information Predicate Device:	Predicate Device: Geistlich Bio-Oss® (K112572, K033815, K970569)	Proposed: Geistlich Bio-Oss
Country of origin of the raw material bovine bone	(b)(4) Trade Secret Process -Product Specs [redacted]	
Appearance	white granulate or white, porous block	white granulate or white, porous block
Moisture	less than 5% (w./w.)	less than 5% (w./w.)
Calcium	35%-40% (w./w.)	35%-40% (w./w.)

Phosphorous	13.5% - 18.5% (w./w.)	13.5% - 18.5% (w./w.)
(b)(4) Trade Secret Process -Product Specs [redacted]		
Heavy metals (as Pb)	less than 20 ppm	less than 20 ppm
Sterility Test	conforms to current USP	conforms to current USP
Bacterial Endotoxins	not more than 20.0 USP EU per vial	not more than 20.0 USP
Material (Chemical) Composition	Hydroxyapatite: unchanged (see Section 15 – Bench Testing)	
Phase Purity	unchanged (see Section 15- Bench Testing) .	
Porosity	unchanged (see Section 15- Bench Testing) .	
Pore Surface Area	unchanged (see Section 15- Bench Testing) .	
Bulk Density	unchanged (see Section 15- Bench Testing) .	
Bimodal pore size distribution	unchanged (see Section 15- Bench Testing) .	
Sterilization	Unchanged	
Labeling	Unchanged	
Manufacturing unchanged	Unchanged	
Quality Control/ Quality Control Procedures	Unchanged	
Intended Use	Unchanged	
Physical Composition	Unchanged	

The sponsor has identified Geistlich Bio-Oss Collagen cleared under K112575, K112572, K092428 and K974399 as the legally marketed predicate device for the Geistlich Bio-Oss Collagen device in the current submission. The sponsor has provided the following comparison table:

Descriptive Information Predicate Device:	**Predicate Device: Geistlich Bio-Oss Collagen® (K112575, K112572, K092428, K974399)**	**Proposed: Geistlich Bio-Oss Collagen®**
Country of origin of the raw material bovine bone	(b)(4) Trade Secret Process -Product Specs [redacted]	
Appearance	white granulate or white, porous block	white sponge-like, hard pieces of customized size
Water	less than 8% (w./w.)	less than 8% (w./w.)
(b)(4) Trade Secret Process -Product Specs [redacted]		
Calcium	38%-42% (w./w.)	38%-42% (w./w.)

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

(b)(4) Trade Secret Process -Product Specs

[redacted]

Sterility Test	conforms to current USP	conforms to current USP
Bacterial Endotoxins	not more than 20.0 USP EU per vial	not more than 20.0 USP EU per vial

(b)(4) Trade Secret Process -Product Specs

[redacted]

Phase Purity	unchanged (see Section 15- Bench Testing) .
Porosity	unchanged (see Section 15- Bench Testing) .
Pore Surface Area	unchanged (see Section 15- Bench Testing) .
Bulk Density	unchanged (see Section 15- Bench Testing) .
Bimodal pore size distribution	unchanged (see Section 15- Bench Testing) .
Sterilization	unchanged (x-ray)
Labeling	Unchanged
Manufacturing unchanged	Unchanged
Quality Control/ Quality Control Procedures	Unchanged
Intended Use	Unchanged
Technological Characteristics	Unchanged
Physical Composition	Unchanged

(b)(4) Trade Secret Process -Product Specs

[redacted]

XIV. Substantial Equivalence Discussion

	Yes	No	
1. Same Indication Statement?	x		If **YES** = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NSE**
3. Same Technological Characteristics?	x		If **YES** = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?			If **YES** = Go To 6
5. Descriptive Characteristics Precise Enough?		x	If **NO** = Go To 8 If **YES** = Stop **SE**
6. New Types Of Safety Or Effectiveness Questions?			If **YES** = Stop **NSE**
7. Accepted Scientific Methods Exist?			If **NO** = Stop **NSE**
8. Performance Data Available?		x	If **NO** = Request Data
9. Data Demonstrate Equivalence?			Final Decision:

(b)(4) Trade Secret Process -Product Specs

[redacted]

(b)(4) Trade Secret Process -Product Specs

[redacted]

(b)(4) Trade Secret Process -Product Specs

[redacted]

(b)(4) Trade Secret Process -Product Specs

[redacted]

Device Description

(b)(4) Trade Secret Process -Product Specs

[redacted]

Shelf Life

(b)(4) Trade Secret Process -Product Specs

[redacted]

Performance Testing – Bench

(b)(4) Trade Secret Process -Product Specs

[redacted]

(b)(4) Trade Secret Process -Product Specs

[redacted]

(b)(4) Trade Secret Process -Product Specs

[redacted]

(b)(4) Trade Secret Process -Product Specs

[redacted]

Performance Testing – Bench

(b)(4) Trade Secret Process -Product Specs

[redacted]

XVI. Contact History

(b)(4) Trade Secret Process -Product Specs

[redacted]

(b)(4) Trade Secret Process -Product Specs

[redacted]

Digital Signature Concurrence Table	
Reviewer Sign-Off Jose L. Moreno Ph.D. Scientific Reviewer	Jose L. Moreno -S 2013.01.02 11:37:05 -05'00'
Branch Chief Sign-Off M. Susan Runner, D.D.S., M.A. Branch Chief Dental Devices	Susan Runner DDS, MA 2013.01.02 11:47:56 -05'00'
Division Sign-Off	Susan Runner DDS, MA 2013.01.02 11:48:51 -05'00'

Moreno, Jose L.

m:	Moreno, Jose L.
Sent:	Wednesday, January 02, 2013 12:06 PM
To:	Daniel.Kracov@aporter.com
Cc:	Runner, Susan
Subject:	K122894/S001
Attachments:	AI K122894-S001.docx
Sensitivity:	Confidential

Premarket Notification [510(k)] Review
Traditional

K122894/S001

Date: January 2nd, 2012
To: The Record Office: ODE
From: Jose Moreno Ph.D., Lead reviewer Division: DAGRID
Through: Dr. Susan Runner, Branch Chief Branch: DDB
510(k) Holder: Geistlich Pharma AG
Device Name: Getistlich Bio-Oss: Natural Bone Grafting Material
Getistlich Bio-Oss Collagen: Natural Bone Grafting Material plus Collagen
Contact: Daniel A. Kracov, Arnold & Porter LLP
Phone: 202-942-5120
Fax: 202-942-5999
Email: Daniel.Kracov@aporter.com

(b)(4) Trade Secret Process -Product Specs

[redacted]

Performance Testing – Bench

(b)(4) Trade Secret Process -Product Specs

[redacted]

510(k) Summary

(b)(4) Trade Secret Process -Product Specs

[redacted]

(b)(4) Trade Secret Process -Product Specs

[redacted]

(b)(4) Trade Secret Process -Product Specs

[redacted]

Regards,

Jose L. Moreno Ph.D.
Scientific Reviewer
Dental Devices Branch
Division of Anesthesiology, General Hospital, Respiratory, Infection Control and Dental Devices
Office of Device Evaluation, Center for Devices and Radiologic Health
10903 New Hampshire Ave Bldg 66 Room 1527
Silver Spring, MD 20993-0002
Phone 301-796-6952
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Jose.Moreno2@fda.hhs.gov

Moreno, Jose L.

ɔm:	Microsoft Outlook
.o:	Daniel.Kracov@aporter.com
Sent:	Wednesday, January 02, 2013 12:06 PM
Subject:	Relayed: K122894/S001

Delivery to these recipients or groups is complete, but no delivery notification was sent by the destination server:

Daniel.Kracov@aporter.com (Daniel.Kracov@aporter.com)

Subject: K122894/S001

* * * COMMUNICATION RESULT REPORT (DEC. 20. 2012 4:45PM) * * *

FAX HEADER 1:
FAX HEADER 2:

TRANSMITTED/STORED : DEC. 20. 2012 4:44PM

FILE	MODE	OPTION	ADDRESS	RESULT	PAGE
2	MEMORY TX		RightFax	OK	1/1

REASON FOR ERROR
E-1) HANG UP OR LINE FAIL
E-2) BUSY
E-3) NO ANSWER
E-4) NO FACSIMILE CONNECTION

DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

December 20, 2012

GEISTLICH PHARMA AG
C/O ARNOLD & PORTER LLP
555 TWELFTH STREET, NW
WASHINGTON, DISTRICT OF COLUMBIA 20004-1206
ATTN: DANIEL A. KRACOV

510k Number: K122894

Product: GEISTLICH BIO-OSS, GEISTLICH B

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Pleaseremember that all correspondence concerning your submission MUST be sent to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely,

510(k) Staff

K122894/S1

ARNOLD & PORTER LLP

Daniel A. Kracov
Daniel.Kracov@aporter.com

202.942.5120
202.942.5999 Fax

555 Twelfth Street, NW
Washington, DC 20004-1206

K 65

December 20, 2012

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: 510(k) Submission # K122894
Response to Questions from Reviewer Jose Moreno, Ph.D. (November 21, 2012)

To Whom it May Concern:

Attached please find responses to the above-referenced questions. This document contains confidential commercial information and/or Trade Secrets that are exempt from disclosure under the Freedom of Information Act, 5 U.S.C. § 552, 21 U.S.C. § 301(y), 21 C.F.R. Part 20, and other applicable laws.

Sincerely,

Daniel A. Kracov

Enclosures

(b)(4) Trade Secret Process -Product Specs

[redacted]

(b)(4) Trade Secret Process -Product Specs

[redacted]

(b)(4) Trade Secret Process -Product Specs

[redacted]

(b)(4) Trade Secret Process -Product Specs

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(b)(4) Trade Secret Process -Product Specs

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(b)(4) Trade Secret Process -Product Specs

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(b)(4) Trade Secret Process -Product Specs

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(b)(4) Trade Secret Process -Product Specs

[redacted]

(b)(4) Trade Secret Process -Product Specs

[redacted]

(b)(4) Trade Secret Process -Product Specs

[redacted]

(b)(4) Trade Secret Process -Product Specs

[redacted]

APPENDICES

Appendix A	(b)(4) Trade Secret Process -Product Specs
Appendix B	Revised Section 15.3 - Performance Testing Bench (HG Pressure Porosimetry)
Appendix C	Revised Section 2 - 510(k) Summary
Appendix D	Revised Section 7 - Executive Summary
Appendix E	Revised Section 8.1 - Device Description (Introduction)
Appendix F	Declarations of Conformity for Biocompatability of Geistlich Bio-Oss® and Geistlich Bio-Oss® Collagen
Appendix G	Kolk A., et al.: Current trends and future perspectives of bone substitute materials - From space holders to innovative biomaterials. J Craniomaxillofac Surg 40: 706-718, 2012
Appendix H	Renders G., et al.: Porosity of human mandibular condylar bone. J Anat 210: 239-248, 2007
Appendix I	Revised Section 15 - Performance Testing Bench (Introduction)

APPENDIX A

(b)(4) Trade Secret Process -Product Specs

[redacted]

(b)(4) Trade Secret Process -Product Specs

[redacted]

(b)(4) Trade Secret Process -Product Specs

[redacted]

(b)(4) Trade Secret Process -Product Specs

[redacted]

(b)(4) Trade Secret Process -Product Specs

[redacted]

(b)(4) Trade Secret Process -Product Specs

[redacted]

(b)(4) Trade Secret Process -Product Specs

[redacted]

APPENDIX B

15.3 HG Pressure Porosimetry

(b)(4) Trade Secret Process -Product Specs

[redacted]

(b)(4) Trade Secret Process -Product Specs

[redacted]

(b)(4) Trade Secret Process -Product Specs

[redacted]

APPENDIX C

2.1 GEISTLICH BIO-OSS®

SPONSOR

Geistlich Pharma AG
Bahnhofstrasse 40
CH-6110 Wolhusen
Switzerland

Contact Person:	Daniel Kracov, Arnold & Porter, LLP
E-mail:	Daniel.Kracov@aporter.com
Phone:	202-942-5120
Fax:	202-942-5999
Date Prepared:	10th Sept., 2012

DEVICE NAME

Proprietary Name:	Geistlich Bio-Oss®
Common/Usual Names:	Natural 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 physically, chemically as well as structurally comparable to the mineralized matrix of human bone.

Geistlich Bio-Oss® is a natural, biocompatible bone mineral matrix, tested for antigenicity, and is manufactured from bovine bone in a validated multistage purification process to remove the organic components without altering the natural structure of the inorganic bone matrix.

Due to the interconnected macro and microporous system the device is highly 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.

2.2 GEISTLICH BIO-OSS COLLAGEN®

SPONSOR

Geistlich Pharma AG
Bahnhofstrasse 40
CH-6110 Wolhusen
Switzerland

Contact Person:	Daniel Kracov, Arnold & Porter, LLP
E-mail:	Daniel.Kracov@aporter.com
Phone:	202-942-5120
Fax:	202-942-5999
Date Prepared:	10th Sept., 2012

DEVICE NAME

Proprietary Name:	Geistlich Bio-Oss Collagen®
Common/Usual Names:	Natural 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. The natural bone mineral granules are physically, chemically as well as structurally comparable to the mineralized matrix of human bone

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

components are removed without altering the natural structure of the inorganic bone matrix.

Due to the interconnected macro and microporous system the device is highly 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
- 1block 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.

APPENDIX D

7.) Executive Summary

Geistlich Bio-Oss® and Geistlich Bio-Oss Collagen® are medical devices used in dental applications for guided bone and tissue regeneration. Geistlich Bio-Oss® consists of highly purified bone mineral and is available as a block or as granules. It serves as a natural porous bone mineral matrix, tested for antigenicity, for augmentation of bone. Geistlich Bio-Oss Collagen® consists of Geistlich Bio-Oss® granules and 10% collagen of porcine origin.

This premarket notification is submitted to receive FDA clearance for an alternative geographic source for the raw material bovine bone used in the production of Geistlich Bio-Oss® and Geistlich Bio-Oss Collagen®.

Currently bovine bone is sourced from (b)(4) which was previously cleared by the FDA under K033815. For commercial reasons Geistlich intends to obtain bovine bone from an additional geographic source - from (b)(4) Trade Secret.

(b)(4) Trade Secret is considered to be free of BSE and according to the World Organization for Animal Health (OIE) is recognized as having a negligible BSE risk (for more details see Section 8.1).

USDA provides a list with countries where BSE exists (*Countries where BSE exists* or *Countries presenting an undue risk of BSE)* on its website (*Countries / Regions Affected with Bovine Spongiform Encephalopathy (BSE)*). (b)(4) Trade Secret is not among the countries presented on this list.[1]

(b)(4) Trade Secret has stringent laws and regulations in place which regulate protection measures against BSE and BSE surveillance to assure that the country will remain free of BSE (for more details see Sections 8.3 and 8.4).

Geistlich meets the FDA recommendations defined in the guidance document *Guidance for FDA Reviewers and Industry: Medical Devices Containing Materials Derived from Animal Sources (Except for In Vitro Diagnostics),* November 6, 1998 regarding the identification, country of origin, traceability and bovine tissue source of the raw material.

Geistlich conducted extensive comparison studies (see Section 15 Performance Testing – Bench) and the physical properties of Geistlich Bio-Oss® manufactured from bovine bone sourced in (b)(4) and Geistlich Bio-Oss® manufactured from bovine bone sourced in (b)(4) Trade Secret were compared by using X-ray diffraction analysis, HG pressure porosimetry and Fourier transform infrared spectroscopy.

---

[1] http://www.aphis.usda.gov/import_export/animals/animal_import/animal_imports_bse.shtml

Based on the generated data it was concluded that the relevant physical properties of Geistlich Bio-Oss® manufactured with bovine bone sourced in (b)(4) Trade Secret Process -Product Specs are identical to Geistlich Bio-Oss® manufactured with bovine bone sourced in (b)(4) Trade Secret Process -Product Specs The data generated for Geistlich Bio-Oss® is equally relevant for Geistlich Bio-Oss Collagen®. Geistlich Bio-Oss Collagen® is a combination of purified spongiosa (cancellous) natural 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 collagen component is resorbed after application.

Geistlich has imposed stringent Quality Controls for sourcing, processing, cleaning, storage, shipment, record keeping and other procedures at the raw material supplier in (b)(4) Trade Secret Process -Product Specs and signed Quality Agreements are in place. Only defined raw material (bone disks of disarticulated bones) will be used for Geistlich which will be used in the further production of Geistlich Bio-Oss® at the Geistlich facilities in Wolhusen, Switzerland (for more detailed information see Section 18.1).

Systems are in place which guarantee full traceability from customer to the batch of raw material and further up to the animal farm from where the animals were taken for slaughtering. And conversely from the batch of raw material that was used in production to the customer that purchased Geistlich Bio-Oss® or Geistlich Bio-Oss Collagen® (for more detailed information see Section 18.1).

Geistlich conducts on site Audits at (b)(4) Trade Secret Process -Product Specs) facilities regularly to control compliance of the supplier to the defined requirements (for more detailed information see Section 18.1).

Conclusion

Relevant national and international institutions such as USDA and OIE confirm that there is no significant risk of BSE in (b)(4) Trade Secret Process - has stringent laws and regulations in place which regulate protection measures against BSE and BSE surveillance to assure that the country will be free of BSE also in the future. In addition the recommendations in the Guidance document: *Medical Devices Containing Materials Derived from Animal Sources (Except for In Vitro Diagnostics),* November 6, 1998 have been met. Sufficient quality control measures for sourcing, processing, cleaning, storage, shipment, record keeping are in place and on site audits are conducted regularly. Therefore Geistlich believes that sourcing of bovine bone from (b)(4) Trade Secret Process -Product Specs for the manufacture of Geistlich Bio-Oss® and Geistlich Bio-Oss Collagen® is as safe as sourcing bovine bone from (b)(4) Trade Secret Process -Product Specs that is currently used for the manufacture of Geistlich Bio-Oss® and Geistlich Bio-Oss Collagen® and that there is no significant risk of BSE transmission when using Geistlich Bio-Oss® or Geistlich Bio-Oss Collagen®.

APPENDIX E

8.) Device Description

8.1 Introduction

Geistlich Bio-Oss® is available as either spongiosa (cancellous) granules or a block. Geistlich Bio-Oss® spongiosa (cancellous) granules and Geistlich Bio- Oss® Block are natural porous bone mineral matrices, tested for antigenicity. They are manufactured by removal of all organic components from bovine bone. Due to its natural structure, Geistlich Bio-Oss® and Geistlich Bio-Oss® Block, are physically and chemically comparable to the mineralized matrix of human bone.

There have been no changes to the method of Geistlich Bio-Oss® manufacture or quality control procedures.

Geistlich Bio-Oss Collagen® is a combination of Geistlich Bio-Oss® granules with 10% collagen. The collagen is added to the product to help improve the handling of the material. The collagen is treated by mincing, drying and defatting it, (b)(4) Trade Secret (b)(4) Trade Secret, as well as washing and rinsing, before being made into a slurry. The slurry is then freeze dried and cleaned. It is then combined with the Geistlich Bio-Oss® granules, made in accordance with the respective 510(k) notifications for that product into blocks of 100 mg, 250 mg and 500 mg, packaged, and sterilized with gamma irradiation.

Currently bovine bone is sourced from (b)(4) which was previously cleared by the FDA under K033815. For commercial reasons Geistlich intends to obtain bovine bones from an additional geographic source - from (b)(4) Trade

There have been no changes to the method of Geistlich Bio-Oss Collagen® manufacture or quality control procedures.

(b)(4) Trade is free of BSE and has implemented stringent laws and regulations, for BSE prevention and surveillance affecting import, traceability and feeding of cattle. The World Organization for Animal Health (OIE), an institution which represents most countries of the world including the USA, has issued a list which was last updated in May, 2012. (b)(4) Trade is listed among the countries with *Negligible BSE* risk which represents the best possible group in terms of risk considerations of BSE (http://www.oie.int/en/animal-health-in-the-world/officialdisease-status/bse/list-of-bse-risk-status/). A copy of the list is provided in Appendix 1.

USDA provides a list with countries where BSE exists (*Countries where BSE exists* or *Countries presenting an undue risk of BSE)* on its website (*Countries /Regions Affected with Bovine Spongiform Encephalopathy (BSE)*). (b)(4) Trade S t P [redacted] is not among the countries presented on this list.2

After evaluation Geistlich concluded that using an alternative geographic source for the manufacture of Geistlich Bio-Oss® and Geistlich Bio-Oss Collagen® does not alter the performance characteristics and does also not raise new questions regarding safety and effectiveness of Geistlich Bio-Oss® or Geistlich Bio-Oss Collagen®.

APPENDIX F

(b)(4) Trade Secret Process -Article

(b)(4) Trade Secret Process -Article

(b)(4) Trade Secret Process -Article

(b)(4) Trade Secret Process -Article

(b)(4) Trade Secret Process -Article

(b)(4) Trade Secret Process -Article

(b)(4) Trade Secret Process -Article

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(b)(4) Trade Secret Process -Article

APPENDIX G

(b)(4) Trade Secret Process -Article

(b)(4) Trade Secret Process -Article

(b)(4) Trade Secret Process -Article

(b)(4) Trade Secret Process -Article

(b)(4) Trade Secret Process -Article

(b)(4) Trade Secret Process -Article

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(b)(4) Trade Secret Process -Article

(b)(4) Trade Secret Process -Article

APPENDIX H

(b)(4) Trade Secret Process -Article

(b)(4) Trade Secret Process -Article

(b)(4) Trade Secret Process -Article

(b)(4) Trade Secret Process -Article

(b)(4) Trade Secret Process -Article

(b)(4) Trade Secret Process -Article

(b)(4) Trade Secret Process -Article

(b)(4) Trade Secret Process -Article

(b)(4) Trade Secret Process -Article

(b)(4) Trade Secret Process -Article

APPENDIX I

15.) Performance Testing – Bench

(b)(4) Trade Secret Process -Testing

[redacted]

K74 K122894/S002

ARNOLD & PORTER LLP

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February 1, 2013

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center - W066-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: K122894/S002
Replacement eCopy

To Whom it May Concern:

On behalf of Geistlich Pharma AG, attached please find a Replacement eCopy for the above submission - K122894/S002. The eCopy is an exact duplicate of the paper copy. This document contains confidential commercial information and/or Trade Secrets that are exempt from disclosure under the Freedom of Information Act, 5 U.S.C. § 552, 21 U.S.C. § 301(y), 21 C.F.R. Part 20, and other applicable laws.

Sincerely,

Daniel A. Kracov
Counsel to Geistlich

Enclosures

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Washington, DC 20004-1206

January 31, 2013

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center - W066-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: 510(k) Submission # K122894
Response to Questions from Jose Moreno, Ph.D. (January 2, 2013)

To Whom it May Concern:

Attached please find responses to the above-referenced questions. This document contains confidential commercial information and/or Trade Secrets that are exempt from disclosure under the Freedom of Information Act, 5 U.S.C. § 552, 21 U.S.C. § 301(y), 21 C.F.R. Part 20, and other applicable laws.

Sincerely,

Daniel A. Kracov
Counsel to Geistlich

Enclosures

(b)(4) Trade Secret Process -Product Specs

[redacted]

(b)(4) Trade Secret Process -Product Specs

[redacted]

(b)(4) Trade Secret Process -Product Specs

[redacted]

(b)(4) Trade Secret Process -Product Specs

[redacted]

(b)(4) Trade Secret Process -Product Specs

[redacted]

(b)(4) Trade Secret Process -Product Specs

[redacted]

APPENDICES

Appendix A	Revised Section 2 - 510(k) Summary
Appendix B	Revised Section 7 - Executive Summary
Appendix C	Revised Section 8.1 - Device Description (Introduction)
Appendix D	Revised Section 15 - Performance Testing Bench (Introduction) and revised Section 15.1 - Performance Testing Bench (X-ray diffraction analysis).
Appendix E	Revised Instructions for Use
Appendix F	Revised Labels (Tray/Outer Box)
Appendix G	Acknowledgment Statement

APPENDIX A

2.1 GEISTLICH BIO-OSS®

SPONSOR

Geistlich Pharma AG
Bahnhofstrasse 40
CH-6110 Wolhusen
Switzerland

Contact Person:	Daniel Kracov, Arnold & Porter, LLP
E-mail:	Daniel.Kracov@aporter.com
Phone:	202-942-5120
Fax:	202-942-5999
Date Prepared:	10th Sept., 2012

DEVICE NAME

Proprietary Name:	Geistlich Bio-Oss®
Common/Usual Names:	~~Natural~~ 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 physically, chemically as well as structurally comparable to the mineralized matrix of human bone.

Geistlich Bio-Oss® is a ~~natural, non-antigenic,~~ biocompatible bone mineral matrix and is manufactured from bovine bone in a validated multistage purification process to remove the organic components ~~without altering the natural structure of the inorganic bone matrix~~.

Due to the interconnected macro and microporous system the device is ~~highly~~ 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.

2.2 GEISTLICH BIO-OSS COLLAGEN®

SPONSOR

Geistlich Pharma AG
Bahnhofstrasse 40
CH-6110 Wolhusen
Switzerland

Contact Person: Daniel Kracov, Arnold & Porter, LLP
E-mail: Daniel.Kracov@aporter.com
Phone: 202-942-5120
Fax: 202-942-5999
Date Prepared: 10th Sept., 2012

DEVICE NAME

Proprietary Name: Geistlich Bio-Oss Collagen®

Common/Usual Names: ~~Natural~~ 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. The ~~natural~~ bone mineral granules are physically, chemically as well as structurally comparable to the mineralized matrix of human bone

Geistlich Bio-Oss Collagen® is a ~~natural, non-antigenic,~~ biocompatible bone mineral matrix and is manufactured from bovine bone and collagen from connective tissue of pigs fit certified for human consumption according to a controlled and validated

multistage purification process. From the bovine bone all organic components are removed ~~without altering the natural structure of the inorganic bone matrix~~.

Due to the interconnected macro and microporous system the device is ~~highly~~ 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
- 1block 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.

2.1 GEISTLICH BIO-OSS®

SPONSOR

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E-mail:	Daniel.Kracov@aporter.com
Phone:	202-942-5120
Fax:	202-942-5999
Date Prepared:	10th Sept., 2012

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 physically, chemically as well as structurally comparable to the mineralized matrix of human bone.

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.

2.2 GEISTLICH BIO-OSS COLLAGEN®

SPONSOR

Geistlich Pharma AG
Bahnhofstrasse 40
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Contact Person: Daniel Kracov, Arnold & Porter, LLP
E-mail: Daniel.Kracov@aporter.com
Phone: 202-942-5120
Fax: 202-942-5999
Date Prepared: 10th Sept., 2012

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. The bone mineral granules are physically, chemically as well as structurally comparable to the mineralized matrix of human bone

Geistlich Bio-Oss Collagen®is a biocompatible bone mineral matrix and is manufactured from bovine bone and collagen from connective tissue of pigs fit 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
- 1block 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

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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.

APPENDIX B

7.) Executive Summary

Geistlich Bio-Oss® and Geistlich Bio-Oss Collagen® are medical devices used in dental applications for guided bone and tissue regeneration. Geistlich Bio-Oss® consists of highly purified bone mineral and is available as a block or as granules. It serves as a ~~natural~~ porous bone mineral matrix~~, tested for antigenicity,~~ for augmentation of bone. Geistlich Bio-Oss Collagen® consists of Geistlich Bio-Oss® granules and 10% collagen of porcine origin.

This premarket notification is submitted to receive FDA clearance for an alternative geographic source for the raw material bovine bone used in the production of Geistlich Bio-Oss® and Geistlich Bio-Oss Collagen®.

Currently bovine bone is sourced from (b)(4) [redacted] which was previously cleared by the FDA under K033815. For commercial reasons Geistlich intends to obtain bovine bone from an additional geographic source - from (b)(4) Trade [redacted].

(b)(4) Trade [redacted] is considered to be free of BSE and according to the World Organization for Animal Health (OIE) is recognized as having a negligible BSE risk (for more details see Section 8.1).

USDA provides a list with countries where BSE exists (*Countries where BSE exists* or *Countries presenting an undue risk of BSE)* on its website (*Countries / Regions Affected with Bovine Spongiform Encephalopathy (BSE)*). (b)(4) Trade [redacted] is not among the countries presented on this list.[1]

(b)(4) Trade [redacted] has stringent laws and regulations in place which regulate protection measures against BSE and BSE surveillance to assure that the country will remain free of BSE (for more details see Sections 8.3 and 8.4).

Geistlich meets the FDA recommendations defined in the guidance document *Guidance for FDA Reviewers and Industry: Medical Devices Containing Materials Derived from Animal Sources (Except for In Vitro Diagnostics)*, November 6, 1998 regarding the identification, country of origin, traceability and bovine tissue source of the raw material.

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[1] http://www.aphis.usda.gov/import_export/animals/animal_import/animal_imports_bse.shtml

Geistlich conducted extensive comparison studies (see Section 15 Performance Testing – Bench) and the physical properties of Geistlich Bio-Oss® manufactured from bovine bone sourced in (b)(4) Trade Secret Process -Product Specs and Geistlich Bio-Oss® manufactured from bovine bone sourced in (b)(4) Trade Secret Process -Product Specs were compared by using X-ray diffraction analysis, HG pressure porosimetry and Fourier transform infrared spectroscopy.

Based on the generated data it was concluded that the relevant physical properties of Geistlich Bio-Oss® manufactured with bovine bone sourced in (b)(4) Trade Secret Process -Product Specs are identical to Geistlich Bio-Oss® manufactured with bovine bone sourced in (b)(4) Trade Secret Process -Product Specs The data generated for Geistlich Bio-Oss® is equally relevant for Geistlich Bio-Oss Collagen®. Geistlich Bio-Oss Collagen® is a combination of purified spongiosa (cancellous) ~~natural~~ 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 collagen component is resorbed after application.

Geistlich has imposed stringent Quality Controls for sourcing, processing, cleaning, storage, shipment, record keeping and other procedures at the raw material supplier in (b)(4) Trade Secret Process -Product Specs and signed Quality Agreements are in place. Only defined raw material (bone disks of disarticulated bones) will be used for Geistlich which will be used in the further production of Geistlich Bio-Oss® at the Geistlich facilities in Wolhusen, Switzerland (for more detailed information see Section 18.1).

Systems are in place which guarantee full traceability from customer to the batch of raw material and further up to the animal farm from where the animals were taken for slaughtering. And conversely from the batch of raw material that was used in production to the customer that purchased Geistlich Bio-Oss® or Geistlich Bio-Oss Collagen® (for more detailed information see Section 18.1).

Geistlich conducts on site Audits at (b)(4) Trade Secret Process -Product Specs facilities regularly to control compliance of the supplier to the defined requirements (for more detailed information see Section 18.1).

Conclusion

Relevant national and international institutions such as USDA and OIE confirm that there is no significant risk of BSE in (b)(4) Trade Secret Process -Product Specs has stringent laws and regulations in place which regulate protection measures against BSE and BSE surveillance to assure that the country will be free of BSE also in the future. In addition the recommendations in the Guidance document:

Medical Devices Containing Materials Derived from Animal Sources (Except for In Vitro Diagnostics), November 6, 1998 have been met. Sufficient quality control measures for sourcing, processing, cleaning, storage, shipment, record keeping are in place and on site audits are conducted regularly. Therefore Geistlich believes that sourcing of bovine bone from (b)(4) Trade Secret [redacted] for the manufacture of Geistlich Bio-Oss® and Geistlich Bio-Oss Collagen® is as safe as sourcing bovine bone from (b)(4) Trade Secret [redacted] that is currently used for the manufacture of Geistlich Bio-Oss® and Geistlich Bio-Oss Collagen® and that there is no significant risk of BSE transmission when using Geistlich Bio-Oss® or Geistlich Bio-Oss Collagen®.

7.) Executive Summary

Geistlich Bio-Oss® and Geistlich Bio-Oss Collagen® are medical devices used in dental applications for guided bone and tissue regeneration. Geistlich Bio-Oss® consists of highly purified bone mineral and is available as a block or as granules. It serves as a porous bone mineral matrix for augmentation of bone. Geistlich Bio-Oss Collagen® consists of Geistlich Bio-Oss® granules and 10% collagen of porcine origin.

This premarket notification is submitted to receive FDA clearance for an alternative geographic source for the raw material bovine bone used in the production of Geistlich Bio-Oss® and Geistlich Bio-Oss Collagen®.

Currently bovine bone is sourced from (b)(4) Trade Secret which was previously cleared by the FDA under K033815. For commercial reasons Geistlich intends to obtain bovine bone from an additional geographic source - from (b)(4) Trade Secret.

(b)(4) Trade Secret is considered to be free of BSE and according to the World Organization for Animal Health (OIE) is recognized as having a negligible BSE risk (for more details see Section 8.1).

USDA provides a list with countries where BSE exists (*Countries where BSE exists* or *Countries presenting an undue risk of BSE)* on its website (*Countries / Regions Affected with Bovine Spongiform Encephalopathy (BSE)*). (b)(4) Trade Secret is not among the countries presented on this list.[1]

(b)(4) Trade Secret has stringent laws and regulations in place which regulate protection measures against BSE and BSE surveillance to assure that the country will remain free of BSE (for more details see Sections 8.3 and 8.4).

Geistlich meets the FDA recommendations defined in the guidance document *Guidance for FDA Reviewers and Industry: Medical Devices Containing Materials Derived from Animal Sources (Except for In Vitro Diagnostics)*, November 6, 1998 regarding the identification, country of origin, traceability and bovine tissue source of the raw material.

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[1] http://www.aphis.usda.gov/import_export/animals/animal_import/animal_imports_bse.shtml

Geistlich conducted extensive comparison studies (see Section 15 Performance Testing – Bench) and the physical properties of Geistlich Bio-Oss® manufactured from bovine bone sourced in (b)(4) Trade Secret Process -Product Specs and Geistlich Bio-Oss® manufactured from bovine bone sourced in (b)(4) Trade Secret Process -Product Specs were compared by using X-ray diffraction analysis, HG pressure porosimetry and Fourier transform infrared spectroscopy.

Based on the generated data it was concluded that the relevant physical properties of Geistlich Bio-Oss® manufactured with bovine bone sourced in (b)(4) Trad are identical to Geistlich Bio-Oss® manufactured with bovine bone sourced in (b)(4) Trade Secret Process -Product Specs The data generated for Geistlich Bio-Oss® is equally relevant for Geistlich Bio-Oss Collagen®. 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 collagen component is resorbed after application.

Geistlich has imposed stringent Quality Controls for sourcing, processing, cleaning, storage, shipment, record keeping and other procedures at the raw material supplier in (b)(4) Trade Secret Process -Product Specs and signed Quality Agreements are in place. Only defined raw material (bone disks of disarticulated bones) will be used for Geistlich which will be used in the further production of Geistlich Bio-Oss® at the Geistlich facilities in Wolhusen, Switzerland (for more detailed information see Section 18.1).

Systems are in place which guarantee full traceability from customer to the batch of raw material and further up to the animal farm from where the animals were taken for slaughtering. And conversely from the batch of raw material that was used in production to the customer that purchased Geistlich Bio-Oss® or Geistlich Bio-Oss Collagen® (for more detailed information see Section 18.1).

Geistlich conducts on site Audits at Affco (b)(4) Trade Secret Process -Product Specs facilities regularly to control compliance of the supplier to the defined requirements (for more detailed information see Section 18.1).

Conclusion

Relevant national and international institutions such as USDA and OIE confirm that there is no significant risk of BSE in (b)(4) Trade Secret Process -Product Specs has stringent laws and regulations in place which regulate protection measures against BSE and BSE surveillance to assure that the country will be free of BSE also in the future. In addition the recommendations in the Guidance document:

Medical Devices Containing Materials Derived from Animal Sources (Except for In Vitro Diagnostics), November 6, 1998 have been met. Sufficient quality control measures for sourcing, processing, cleaning, storage, shipment, record keeping are in place and on site audits are conducted regularly. Therefore Geistlich believes that sourcing of bovine bone from (b)(4) Trade Secret [redacted] for the manufacture of Geistlich Bio-Oss® and Geistlich Bio-Oss Collagen® is as safe as sourcing bovine bone from (b)(4) Trade [redacted] that is currently used for the manufacture of Geistlich Bio-Oss® and Geistlich Bio-Oss Collagen® and that there is no significant risk of BSE transmission when using Geistlich Bio-Oss® or Geistlich Bio-Oss Collagen®.

APPENDIX C

8.) Device Description

8.1 Introduction

Geistlich Bio-Oss® is available as either spongiosa (cancellous) granules or a block. Geistlich Bio-Oss® spongiosa (cancellous) granules and Geistlich Bio-Oss® Block are ~~natural~~ porous bone mineral matrices~~, tested for antigenicity~~. They are manufactured by removal of all organic components from bovine bone. Due to its ~~natural~~ structure, Geistlich Bio-Oss® and Geistlich Bio-Oss® Block, are physically and chemically comparable to the mineralized matrix of human bone.

There have been no changes to the method of Geistlich Bio-Oss® manufacture or quality control procedures.

Geistlich Bio-Oss Collagen® is a combination of Geistlich Bio-Oss® granules with 10% collagen. The collagen is added to the product to help improve the handling of the material. The collagen is treated by mincing, drying and defatting it, (b)(4) Trade Secret Process -Product Specs as well as washing and rinsing, before being made into a slurry. The slurry is then freeze dried and cleaned. It is then combined with the Geistlich Bio-Oss® granules, made in accordance with the respective 510(k) notifications for that product into blocks of 100 mg, 250 mg and 500 mg, packaged, and sterilized with gamma irradiation.

Currently bovine bone is sourced from (b)(4) which was previously cleared by the FDA under K033815. For commercial reasons Geistlich intends to obtain bovine bones from an additional geographic source - from (b)(4) Trade Secret.

There have been no changes to the method of Geistlich Bio-Oss Collagen® manufacture or quality control procedures.

(b)(4) Trade Secret is free of BSE and has implemented stringent laws and regulations, for BSE prevention and surveillance affecting import, traceability and feeding of cattle. The World Organization for Animal Health (OIE), an institution which represents most countries of the world including the USA, has issued a list which was last updated in May, 2012. (b)(4) Trade Secret is listed among the countries with *Negligible BSE* risk which represents the best possible group in terms of risk considerations of BSE (http://www.oie.int/en/animal-health-in-the-world/official-disease-status/bse/list-of-bse-risk-status/). A copy of the list is provided in Appendix 1.

8.) Device Description

8.1 Introduction

Geistlich Bio-Oss® is available as either spongiosa (cancellous) granules or a block. Geistlich Bio-Oss® spongiosa (cancellous) granules and Geistlich Bio-Oss® Block are porous bone mineral matrices. They are manufactured by removal of all organic components from bovine bone. Due to its structure, Geistlich Bio-Oss® and Geistlich Bio-Oss® Block, are physically and chemically comparable to the mineralized matrix of human bone.

There have been no changes to the method of Geistlich Bio-Oss® manufacture or quality control procedures.

Geistlich Bio-Oss Collagen® is a combination of Geistlich Bio-Oss® granules with 10% collagen. The collagen is added to the product to help improve the handling of the material. The collagen is treated by mincing, drying and defatting it, [redacted] as well as washing and rinsing, before being made into a slurry. The slurry is then freeze dried and cleaned. It is then combined with the Geistlich Bio-Oss® granules, made in accordance with the respective 510(k) notifications for that product into blocks of 100 mg, 250 mg and 500 mg, packaged, and sterilized with gamma irradiation.

Currently bovine bone is sourced from [redacted] which was previously cleared by the FDA under K033815. For commercial reasons Geistlich intends to obtain bovine bones from an additional geographic source - from [redacted]

There have been no changes to the method of Geistlich Bio-Oss Collagen® manufacture or quality control procedures.

[redacted] is free of BSE and has implemented stringent laws and regulations, for BSE prevention and surveillance affecting import, traceability and feeding of cattle. The World Organization for Animal Health (OIE), an institution which represents most countries of the world including the USA, has issued a list which was last updated in May, 2012. [redacted] is listed among the countries with *Negligible BSE* risk which represents the best possible group in terms of risk considerations of BSE (http://www.oie.int/en/animal-health-in-the-world/official-disease-status/bse/list-of-bse-risk-status/). A copy of the list is provided in Appendix 1.

APPENDIX D

15.) Performance Testing – Bench

(b)(4) Trade Secret Process -Testing

[redacted]

15.) Performance Testing – Bench

(b)(4) Trade Secret Process -Testing

[redacted]

APPENDIX E

GEISTLICH BIO-OSS®
~~Natural~~ Bone Grafting Material

Geistlich Bio-Oss® is a sterile, biocompatible ~~natural~~ porous bone mineral for use in periodontal, and oral and maxillofacial surgery.

DESCRIPTION:
Geistlich Bio-Oss® is a ~~natural, non-antigenic,~~ porous bone mineral matrix. It is produced by removal of all organic components from bovine bone. Due to its ~~natural~~ structure Geistlich Bio-Oss® is physically and chemically comparable to the mineralized matrix of human bone. It is available in spongiosa (cancellous) granules and blocks. Geistlich Bio-Oss® is sterilized by γ-irradiation.

PROPERTIES / ACTIONS:
Geistlich Bio-Oss®: The anorganic bone matrix of Geistlich Bio-Oss® has macro- and microscopic structures similar to human bone. The formation and ingrowth of new bone at the implantation site of Geistlich Bio-Oss® is favored, due to its trabecular architecture, interconnecting macro and micro pores and its ~~natural~~ consistency..

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

CONTRAINDICATIONS:
Geistlich Bio-Oss should not be used in the presence of infected wounds.

DIRECTIONS FOR USE:
The general principles of sterile handling and patient medication must be followed when using Geistlich Bio-Oss®.
- The filling of periodontal defects with Geistlich Bio-Oss® requires successful treatment of the periodontal lesion (root planing, debridement) prior to the implantation. The defect should be covered with a membrane (e.g., Geistlich Bio-Gide®) for optimal tissue regeneration.
- After exposure of the bony defect with mucoperiosteal flap, all granulation tissue must be carefully removed.
- Mix Geistlich Bio-Oss® granulate with the patient's blood or with physiological saline solution before the implantation.
- The material should be placed in direct contact with well vascularized, bleeding bone surfaces. Cortical bone should be mechanically perforated to facilitate ingrowth of new blood vessels and bone forming cells.
- Application:
  - Geistlich Bio-Oss® granulate is placed into the defect, using sterile instruments (spatula, spoon or syringe). Use of excessive force will result in crushing of particles and loss of trabecular architecture.
  - Geistlich Bio-Oss® spongiosa (cancellous) bone blocks may be adapted to the desired size with a scalpel and placed into the bone cavity. If necessary, the block may be moistened with the patient's blood or with physiological saline solution.
  . The shaped block is then placed loosely into the bone cavity in direct contact with well vascularized and bleeding bone.
- *In situ* modeling may be performed with a sterile spatula or other suitable instrument.
- Overfilling of the defects should be avoided.
- It is advisable to cover Geistlich Bio-Oss® with a membrane barrier (e.g., Geistlich Bio-Gide®).
- When closing the wound, the soft tissue flap should completely cover the implanted Geistlich Bio-Oss®, and should be fixed by sutures.
- If primary wound closure cannot be achieved completely, further mobilization of the flap (incision through the periosteum) should be performed.
- A surgical dressing may be placed over the wound for one to two weeks.
- Sites grafted with Geistlich Bio-Oss® should be allowed to heal approximately 6 months prior to implant placement.
- A basic requirement for successful periodontal treatment includes control of any bacterial infection as well as thorough oral hygiene. It is advised that, preceding the surgical intervention, there be a hygiene phase, which would include proper instruction for the patient. A postoperative maintenance phase can ensure long-term therapeutic success.

GEISTLICH BIO-OSS®
~~Natural~~ Bone Grafting Material

PRECAUTIONS:
Geistlich Bio-Oss® should only be used by trained dentists or oral surgeons.

In order to facilitate the formation of new bone Geistlich Bio-Oss® should only be implanted in direct contact with a well vascularized bony tissue (selective osteoplasty of adjacent cortical bone may be necessary).
In larger defects a mixture of autogenous bone or bone marrow may improve the formation of new bone.
The implantation of titanium fixtures should not take place until about 6 months after the use of Geistlich Bio-Oss® in any implant site.
Geistlich Bio-Oss® should be used with special caution in patients with:

- Metabolic diseases (diabetes, hyperparathyroidism, osteomalacia)
- Osteoporosis
- Severe renal dysfunction, severe liver disease
- High dose therapy with corticosteroids
- Vascular impairment at the implant site
- Autoimmune disease
- Radiotherapy
- Heavy smoking

Effect on pregnant or lactating women is not known.

ADVERSE REACTIONS:
Incompatibility reactions with Geistlich Bio-Oss® cannot be excluded. Possible complications which may occur with any surgery include swelling at the surgical site, flap sloughing, bleeding, local inflammation, bone loss, infection or pain.

STORAGE AND HANDLING:
If the sterile packaging is damaged or opened, the product must not be used. The contents of the blister package or bottle are designed for single use only. Discard any unused material after opening. Resterilization is not possible. Do not use after the expiration date. Store at controlled room temperature 15°-25°C (59°-77°F) and in a dry place.

PRESENTATION:

Re-Order No.	Product	Weight	Particle Size
20111	Geistlich Bio-Oss® spongiosa (cancellous) granules	0.25g	0.25 - 1.0mm
20112	Geistlich Bio-Oss® spongiosa (cancellous) granules	0.5 g	0.25 - 1.0mm
20113	Geistlich Bio-Oss® spongiosa (cancellous) granules	2.0 g	0.25 - 1.0mm
20114	Geistlich Bio-Oss® spongiosa (cancellous) granules	5.0 g	0.25 - 1.0mm
20121	Geistlich Bio-Oss® spongiosa (cancellous) granules	0.5 g	1.0 - 2.0mm
20122	Geistlich Bio-Oss® spongiosa (cancellous) granules	2.0 g	1.0 - 2.0mm

Re-Order No.	Product	Block size (approx.)
20131	Geistlich Bio-Oss® spongiosa (cancellous) block	1x1x2cm

Distributed by:
Geistlich Pharma North America Inc.
Princeton, New Jersey 08540
1-(855) 799-5500
www.geistlich-na.com

Manufacturer:
Geistlich Pharma AG
CH-6110 Wolhusen
Switzerland

Made in Switzerland

CAUTION: Federal law restricts this device to sale by or on the order of a dentist or physician.

package insert: www.geistlich-na.com

IN0712
937010/0508

GEISTLICH BIO-OSS®
Bone Grafting Material

Geistlich Bio-Oss® is a sterile, biocompatible porous bone mineral for use in periodontal, and oral and maxillofacial surgery.

DESCRIPTION:
Geistlich Bio-Oss® is a porous bone mineral matrix. It is produced by removal of all organic components from bovine bone. Due to its structure Geistlich Bio-Oss® is physically and chemically comparable to the mineralized matrix of human bone. It is available in spongiosa (cancellous) granules and blocks. Geistlich Bio-Oss® is sterilized by γ -irradiation.

PROPERTIES / ACTIONS:
Geistlich Bio-Oss®: The anorganic bone matrix of Geistlich Bio-Oss® has macro- and microscopic structures similar to human bone. The formation and ingrowth of new bone at the implantation site of Geistlich Bio-Oss® is favored, due to its trabecular architecture, interconnecting macro and micro pores and its consistency..

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

CONTRAINDICATIONS:
Geistlich Bio-Oss should not be used in the presence of infected wounds.

DIRECTIONS FOR USE:
The general principles of sterile handling and patient medication must be followed when using Geistlich Bio-Oss®.
- The filling of periodontal defects with Geistlich Bio-Oss® requires successful treatment of the periodontal lesion (root planing, debridement) prior to the implantation. The defect should be covered with a membrane (e.g., Geistlich Bio-Gide®) for optimal tissue regeneration.
- After exposure of the bony defect with mucoperiosteal flap, all granulation tissue must be carefully removed.
- Mix Geistlich Bio-Oss® granulate with the patient's blood or with physiological saline solution before the implantation.
- The material should be placed in direct contact with well vascularized, bleeding bone surfaces. Cortical bone should be mechanically perforated to facilitate ingrowth of new blood vessels and bone forming cells.
- Application:
  - Geistlich Bio-Oss® granulate is placed into the defect, using sterile instruments (spatula, spoon or syringe). Use of excessive force will result in crushing of particles and loss of trabecular architecture.
  - Geistlich Bio-Oss® spongiosa (cancellous) bone blocks may be adapted to the desired size with a scalpel and placed into the bone cavity. If necessary, the block may be moistened with the patient's blood or with physiological saline solution. The shaped block is then placed loosely into the bone cavity in direct contact with well vascularized and bleeding bone.
- *In situ* modeling may be performed with a sterile spatula or other suitable instrument.
- Overfilling of the defects should be avoided.
- It is advisable to cover Geistlich Bio-Oss® with a membrane barrier (e.g., Geistlich Bio-Gide®).
- When closing the wound, the soft tissue flap should completely cover the implanted Geistlich Bio-Oss®, and should be fixed by sutures.
- If primary wound closure cannot be achieved completely, further mobilization of the flap (incision through the periosteum) should be performed.
- A surgical dressing may be placed over the wound for one to two weeks.
- Sites grafted with Geistlich Bio-Oss® should be allowed to heal approximately 6 months prior to implant placement.
- A basic requirement for successful periodontal treatment includes control of any bacterial infection as well as thorough oral hygiene. It is advised that, preceding the surgical intervention, there be a hygiene phase, which would include proper instruction for the patient. A postoperative maintenance phase can ensure long-term therapeutic success.

GEISTLICH BIO-OSS®
Bone Grafting Material

PRECAUTIONS:
Geistlich Bio-Oss® should only be used by trained dentists or oral surgeons.

In order to facilitate the formation of new bone Geistlich Bio-Oss® should only be implanted in direct contact with a well vascularized bony tissue (selective osteoplasty of adjacent cortical bone may be necessary).
In larger defects a mixture of autogenous bone or bone marrow may improve the formation of new bone.
The implantation of titanium fixtures should not take place until about 6 months after the use of Geistlich Bio-Oss® in any implant site.
Geistlich Bio-Oss® should be used with special caution in patients with:

- Metabolic diseases (diabetes, hyperparathyroidism, osteomalacia)
- Osteoporosis
- Severe renal dysfunction, severe liver disease
- High dose therapy with corticosteroids
- Vascular impairment at the implant site
- Autoimmune disease
- Radiotherapy
- Heavy smoking

Effect on pregnant or lactating women is not known.

ADVERSE REACTIONS:
Incompatibility reactions with Geistlich Bio-Oss® cannot be excluded. Possible complications which may occur with any surgery include swelling at the surgical site, flap sloughing, bleeding, local inflammation, bone loss, infection or pain.

STORAGE AND HANDLING:
If the sterile packaging is damaged or opened, the product must not be used. The contents of the blister package or bottle are designed for single use only. Discard any unused material after opening. Resterilization is not possible. Do not use after the expiration date. Store at controlled room temperature 15°-25°C (59°-77°F) and in a dry place.

PRESENTATION:

Re-Order No.	Product	Weight	Particle Size
20111	Geistlich Bio-Oss® spongiosa (cancellous) granules	0.25g	0.25 - 1.0mm
20112	Geistlich Bio-Oss® spongiosa (cancellous) granules	0.5 g	0.25 - 1.0mm
20113	Geistlich Bio-Oss® spongiosa (cancellous) granules	2.0 g	0.25 - 1.0mm
20114	Geistlich Bio-Oss® spongiosa (cancellous) granules	5.0 g	0.25 - 1.0mm
20121	Geistlich Bio-Oss® spongiosa (cancellous) granules	0.5 g	1.0 - 2.0mm
20122	Geistlich Bio-Oss® spongiosa (cancellous) granules	2.0 g	1.0 - 2.0mm

Re-Order No.	Product	Block size (approx.)
20131	Geistlich Bio-Oss® spongiosa (cancellous) block	1x1x2cm

Distributed by:
Geistlich Pharma North America Inc.
Princeton, New Jersey 08540
1-(855) 799-5500
www.geistlich-na.com

Manufacturer:
Geistlich Pharma AG
CH-6110 Wolhusen
Switzerland

Made in Switzerland

CAUTION: Federal law restricts this device to sale by or on the order of a dentist or physician.

package insert: www.geistlich-na.com

IN0712
937010/0508

GEISTLICH BIO-OSS® / GEISTLICH BIO-OSS PEN®
~~Natural~~ Bone Grafting Material

Geistlich Bio-Oss® is a sterile, biocompatible ~~natural~~ porous bone mineral for use in periodontal, and oral and maxillofacial surgery.

DESCRIPTION:
Geistlich Bio-Oss® is a ~~natural, non-antigenic,~~ porous bone mineral matrix. It is produced by removal of all organic components from bovine bone. Due to its ~~natural~~ structure Geistlich Bio-Oss® is physically and chemically comparable to the mineralized matrix of human bone. It is available in spongiosa (cancellous) granules and blocks. Geistlich Bio-Oss® is sterilized by gamma -irradiation.

PROPERTIES / ACTIONS:
The anorganic bone matrix of Geistlich Bio-Oss® has macro- and microscopic structures similar to human bone. The formation and ingrowth of new bone at the implantation site of Geistlich Bio-Oss® is favored, due to its trabecular architecture, interconnecting macro and micro pores and its ~~natural~~ consistency.

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

CONTRAINDICATIONS:
Geistlich Bio-Oss should not be used in the presence of infected wounds.

DIRECTIONS FOR USE:
The general principles of sterile handling and patient medication must be followed when using Geistlich Bio-Oss®.
- The filling of periodontal defects with Geistlich Bio-Oss® requires successful treatment of the periodontal lesion (root planing, debridement) prior to the implantation. The defect should be covered with a membrane (e.g., Geistlich Bio-Gide®) for optimal tissue regeneration.
- After exposure of the bony defect with mucoperiosteal flap, all granulation tissue must be carefully removed.
- The material should be placed in direct contact with well vascularized, bleeding bone surfaces. Cortical bone should be mechanically perforated to facilitate ingrowth of new blood vessels and bone forming cells.
- Application:
  a) Geistlich Bio-Oss Pen® spongiosa (cancellous) granules: Please see pictograms at the end of the page or on the package label to follow the instruction below.
  1. Holding the Geistlich Bio-Oss Pen® firmly, tear off the protective seal (A) and unscrew the protection cap (B). This exposes the applicator and filter cap.
  2. Do not remove the red/green filter cap from the applicator at this time.
  3. For complete wetting of Geistlich Bio-Oss®, hold the applicator with both hands and place the filter cap into the sterile physiological saline solution or the patient's blood. Completely retract the plunger. For 0.5 cc applicator, one retraction is sufficient to complete wetting of Geistlich Bio-Oss®. For 1.0 cc and 1.5 cc applicators, depress the plunger, using thumb pressure, to eject the wetting fluid without compressing Geistlich Bio-Oss®. Re-wet with the same wetting fluid by retracting and depressing the plunger approximately 5 times. Alternatively, use a separate syringe (not included) to wet Geistlich Bio-Oss®. Directly inject the wetting fluid of choice through the filter cap into the Geistlich Bio-Oss® granules.
  4. Once wetted, gently depress the plunger to eject any excess fluid.
  5. Remove the filter cap from the applicator (A). Attach the curved applicator tip by screwing it on to the end of the applicator (B). The applicator is now ready for use. Using thumb pressure, depress the plunger and apply Geistlich Bio-Oss® directly to the surgical site.
  b) Geistlich Bio-Oss® spongiosa (cancellous) granules in vials: Mix Geistlich Bio-Oss® granulate with the patient's blood or with physiological saline solution before the implantation..The granulate is placed into the defect, using sterile instruments (spatula or spoon). Use of excessive force will result in crushing of particles and loss of trabecular architecture.
  c) Geistlich Bio-Oss® spongiosa (cancellous) bone block: The Geistlich Bio-Oss® block may be adapted to the desired size with a scalpel and placed into the bone cavity. If necessary, the block may be moistened with the patient's blood or with physiological saline solution. The shaped block is then placed loosely into the bone cavity in direct contact with well vascularized and bleeding bone.
- *In situ* modeling may be performed with a sterile spatula or other suitable instrument.
- Overfilling of the defects should be avoided.
- It is advisable to cover Geistlich Bio-Oss® with a membrane barrier (e.g., Geistlich Bio-Gide®).
- When closing the wound, the soft tissue flap should completely cover the implanted Geistlich Bio-Oss®, and should be fixed by sutures.
- If primary wound closure cannot be achieved completely, further mobilization of the flap (incision through the periosteum) should be performed.
- A surgical dressing may be placed over the wound for one to two weeks.
- Sites grafted with Geistlich Bio-Oss® should be allowed to heal approximately 6 months prior to implant placement.
- A basic requirement for successful periodontal treatment includes control of any bacterial infection as well as thorough oral hygiene. It is advised that, preceding the surgical intervention, there be a hygiene phase, which would include proper instruction for the patient. A postoperative maintenance phase can ensure long-term therapeutic success.

GEISTLICH BIO-OSS® / GEISTLICH BIO-OSS PEN®
~~Natural~~ Bone Grafting Material

PRECAUTIONS:
Geistlich Bio-Oss® should only be used by trained dentists or oral surgeons.

In order to facilitate the formation of new bone Geistlich Bio-Oss® should only be implanted in direct contact with a well vascularized bony tissue (selective osteoplasty of adjacent cortical bone may be necessary).
In larger defects a mixture of autogenous bone or bone marrow may improve the formation of new bone.
The implantation of titanium fixtures should not take place until about 6 months after the use of Geistlich Bio-Oss® in any implant site.
Geistlich Bio-Oss® should be used with special caution in patients with:

- Metabolic diseases (diabetes, hyperparathyroidism, osteomalacia)
- Osteoporosis
- Severe renal dysfunction, severe liver disease
- High dose therapy with corticosteroids
- Vascular impairment at the implant site
- Autoimmune disease
- Radiotherapy
- Heavy smoking

Effect on pregnant or lactating women is not known.

ADVERSE REACTIONS:
Incompatibility reactions with Geistlich Bio-Oss® cannot be excluded. Possible complications which may occur with any surgery include swelling at the surgical site, flap sloughing, bleeding, local inflammation, bone loss, infection or pain.

STORAGE AND HANDLING:
If the sterile packaging is damaged or opened, the product must not be used. The contents of the blister package or bottle are designed for single use only. Discard any unused material after opening. Resterilization is not possible. Do not use after the expiration date. Store at controlled room temperature 15°-25°C (59°-77°F) and in a dry place.

PRESENTATION:

Re-Order No.	Product	Weight	Particle Size
20115	Geistlich Bio-Oss Pen® spongiosa (cancellous) granules	0.25g	0.25 - 1.0mm
20116	Geistlich Bio-Oss Pen® spongiosa (cancellous) granules	0.5 g	0.25 - 1.0mm
20126	Geistlich Bio-Oss Pen® spongiosa (cancellous) granules	0.5 g	1.0 - 2.0mm

Re-Order No.	Product	Weight	Particle Size
20111	Geistlich Bio-Oss® spongiosa (cancellous) granules	0.25g	0.25 - 1.0mm
20112	Geistlich Bio-Oss® spongiosa (cancellous) granules	0.5 g	0.25 - 1.0mm
20113	Geistlich Bio-Oss® spongiosa (cancellous) granules	2.0 g	0.25 - 1.0mm
20114	Geistlich Bio-Oss® spongiosa (cancellous) granules	5.0 g	0.25 - 1.0mm
20121	Geistlich Bio-Oss® spongiosa (cancellous) granules	0.5 g	1.0 - 2.0mm
20122	Geistlich Bio-Oss® spongiosa (cancellous) granules	2.0 g	1.0 - 2.0mm

Re-Order No.	Product	Block size (approx.)
20131	Geistlich Bio-Oss® spongiosa (cancellous) block	1x1x2cm

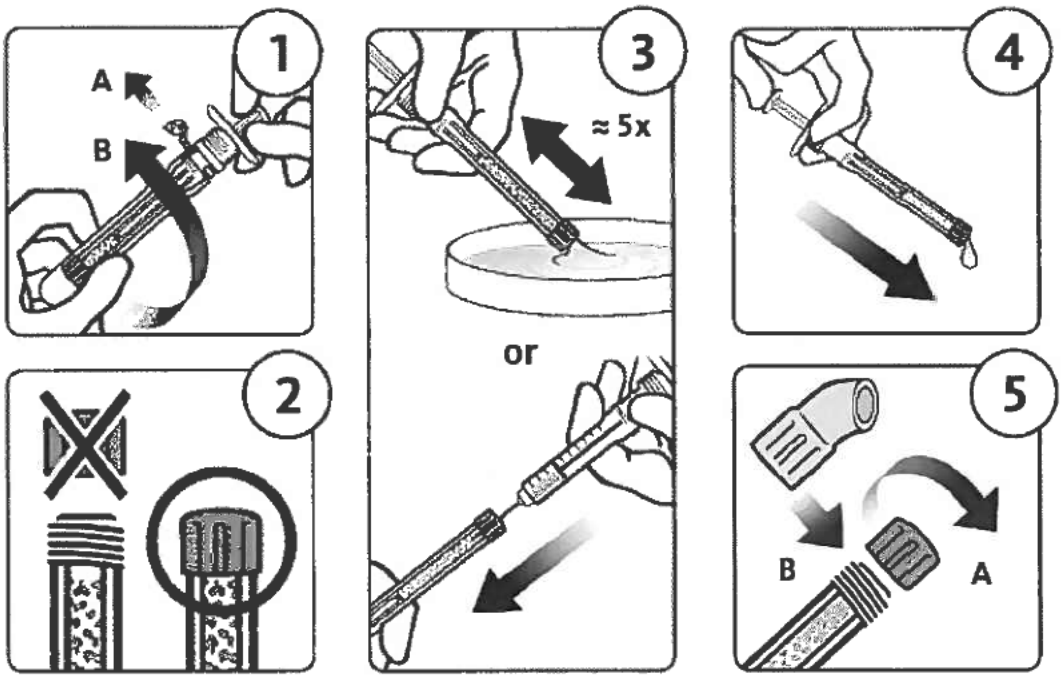
Distributed by:
Geistlich Pharma North America Inc.
Princeton, New Jersey 08540
1-(855) 799-5500
www.geistlich-na.com

Manufacturer:
Geistlich Pharma AG
CH-6110 Wolhusen
Switzerland

Made in Switzerland

CAUTION: Federal law restricts this device to sale by or on the order of a dentist or physician.

package insert: www.geistlich-na.com


1
A
B
2
3
≈ 5x
or
4
5
B
A

GEISTLICH BIO-OSS® / GEISTLICH BIO-OSS PEN®
Bone Grafting Material

Geistlich Bio-Oss® is a sterile, biocompatible porous bone mineral for use in periodontal, and oral and maxillofacial surgery.

DESCRIPTION:
Geistlich Bio-Oss® is a porous bone mineral matrix. It is produced by removal of all organic components from bovine bone. Due to its structure Geistlich Bio-Oss® is physically and chemically comparable to the mineralized matrix of human bone. It is available in spongiosa (cancellous) granules and blocks. Geistlich Bio-Oss® is sterilized by gamma -irradiation.

PROPERTIES / ACTIONS:
The anorganic bone matrix of Geistlich Bio-Oss® has macro- and microscopic structures similar to human bone. The formation and ingrowth of new bone at the implantation site of Geistlich Bio-Oss® is favored, due to its trabecular architecture, interconnecting macro and micro pores and its consistency.

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

CONTRAINDICATIONS:
Geistlich Bio-Oss should not be used in the presence of infected wounds.

DIRECTIONS FOR USE:
The general principles of sterile handling and patient medication must be followed when using Geistlich Bio-Oss®.
- The filling of periodontal defects with Geistlich Bio-Oss® requires successful treatment of the periodontal lesion (root planing, debridement) prior to the implantation. The defect should be covered with a membrane (e.g., Geistlich Bio-Gide®) for optimal tissue regeneration.
- After exposure of the bony defect with mucoperiosteal flap, all granulation tissue must be carefully removed.
- The material should be placed in direct contact with well vascularized, bleeding bone surfaces. Cortical bone should be mechanically perforated to facilitate ingrowth of new blood vessels and bone forming cells.
- Application:
  a) Geistlich Bio-Oss Pen® spongiosa (cancellous) granules: Please see pictograms at the end of the page or on the package label to follow the instruction below.
  1. Holding the Geistlich Bio-Oss Pen® firmly, tear off the protective seal (A) and unscrew the protection cap (B). This exposes the applicator and filter cap.
  2. Do not remove the red/green filter cap from the applicator at this time.
  3. For complete wetting of Geistlich Bio-Oss®, hold the applicator with both hands and place the filter cap into the sterile physiological saline solution or the patient's blood. Completely retract the plunger. For 0.5 cc applicator, one retraction is sufficient to complete wetting of Geistlich Bio-Oss®. For 1.0 cc and 1.5 cc applicators, depress the plunger, using thumb pressure, to eject the wetting fluid without compressing Geistlich Bio-Oss®. Re-wet with the same wetting fluid by retracting and depressing the plunger approximately 5 times. Alternatively, use a separate syringe (not included) to wet Geistlich Bio-Oss®. Directly inject the wetting fluid of choice through the filter cap into the Geistlich Bio-Oss® granules.
  4. Once wetted, gently depress the plunger to eject any excess fluid.
  5. Remove the filter cap from the applicator (A). Attach the curved applicator tip by screwing it on to the end of the applicator (B). The applicator is now ready for use. Using thumb pressure, depress the plunger and apply Geistlich Bio-Oss® directly to the surgical site.
  b) Geistlich Bio-Oss® spongiosa (cancellous) granules in vials: Mix Geistlich Bio-Oss® granulate with the patient's blood or with physiological saline solution before the implantation..The granulate is placed into the defect, using sterile instruments (spatula or spoon). Use of excessive force will result in crushing of particles and loss of trabecular architecture.
  c) Geistlich Bio-Oss® spongiosa (cancellous) bone block: The Geistlich Bio-Oss® block may be adapted to the desired size with a scalpel and placed into the bone cavity. If necessary, the block may be moistened with the patient's blood or with physiological saline solution. The shaped block is then placed loosely into the bone cavity in direct contact with well vascularized and bleeding bone.
- *In situ* modeling may be performed with a sterile spatula or other suitable instrument.
- Overfilling of the defects should be avoided.
- It is advisable to cover Geistlich Bio-Oss® with a membrane barrier (e.g., Geistlich Bio-Gide®).
- When closing the wound, the soft tissue flap should completely cover the implanted Geistlich Bio-Oss®, and should be fixed by sutures.
- If primary wound closure cannot be achieved completely, further mobilization of the flap (incision through the periosteum) should be performed.
- A surgical dressing may be placed over the wound for one to two weeks.
- Sites grafted with Geistlich Bio-Oss® should be allowed to heal approximately 6 months prior to implant placement.
- A basic requirement for successful periodontal treatment includes control of any bacterial infection as well as thorough oral hygiene. It is advised that, preceding the surgical intervention, there be a hygiene phase, which would include proper instruction for the patient. A postoperative maintenance phase can ensure long-term therapeutic success.

GEISTLICH BIO-OSS® / GEISTLICH BIO-OSS PEN®
Bone Grafting Material

PRECAUTIONS:
Geistlich Bio-Oss® should only be used by trained dentists or oral surgeons.

In order to facilitate the formation of new bone Geistlich Bio-Oss® should only be implanted in direct contact with a well vascularized bony tissue (selective osteoplasty of adjacent cortical bone may be necessary).
In larger defects a mixture of autogenous bone or bone marrow may improve the formation of new bone.
The implantation of titanium fixtures should not take place until about 6 months after the use of Geistlich Bio-Oss® in any implant site.
Geistlich Bio-Oss® should be used with special caution in patients with:

- Metabolic diseases (diabetes, hyperparathyroidism, osteomalacia)
- Osteoporosis
- Severe renal dysfunction, severe liver disease
- High dose therapy with corticosteroids
- Vascular impairment at the implant site
- Autoimmune disease
- Radiotherapy
- Heavy smoking

Effect on pregnant or lactating women is not known.

ADVERSE REACTIONS:
Incompatibility reactions with Geistlich Bio-Oss® cannot be excluded. Possible complications which may occur with any surgery include swelling at the surgical site, flap sloughing, bleeding, local inflammation, bone loss, infection or pain.

STORAGE AND HANDLING:
If the sterile packaging is damaged or opened, the product must not be used. The contents of the blister package or bottle are designed for single use only. Discard any unused material after opening. Resterilization is not possible. Do not use after the expiration date. Store at controlled room temperature 15°-25°C (59°-77°F) and in a dry place.

PRESENTATION:

Re-Order No.	Product	Weight	Particle Size
20115	Geistlich Bio-Oss Pen® spongiosa (cancellous) granules	0.25g	0.25 - 1.0mm
20116	Geistlich Bio-Oss Pen® spongiosa (cancellous) granules	0.5 g	0.25 - 1.0mm
20126	Geistlich Bio-Oss Pen® spongiosa (cancellous) granules	0.5 g	1.0 - 2.0mm

Re-Order No.	Product	Weight	Particle Size
20111	Geistlich Bio-Oss® spongiosa (cancellous) granules	0.25g	0.25 - 1.0mm
20112	Geistlich Bio-Oss® spongiosa (cancellous) granules	0.5 g	0.25 - 1.0mm
20113	Geistlich Bio-Oss® spongiosa (cancellous) granules	2.0 g	0.25 - 1.0mm
20114	Geistlich Bio-Oss® spongiosa (cancellous) granules	5.0 g	0.25 - 1.0mm
20121	Geistlich Bio-Oss® spongiosa (cancellous) granules	0.5 g	1.0 - 2.0mm
20122	Geistlich Bio-Oss® spongiosa (cancellous) granules	2.0 g	1.0 - 2.0mm

Re-Order No.	Product	Block size (approx.)
20131	Geistlich Bio-Oss® spongiosa (cancellous) block	1x1x2cm

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Manufacturer:
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Switzerland

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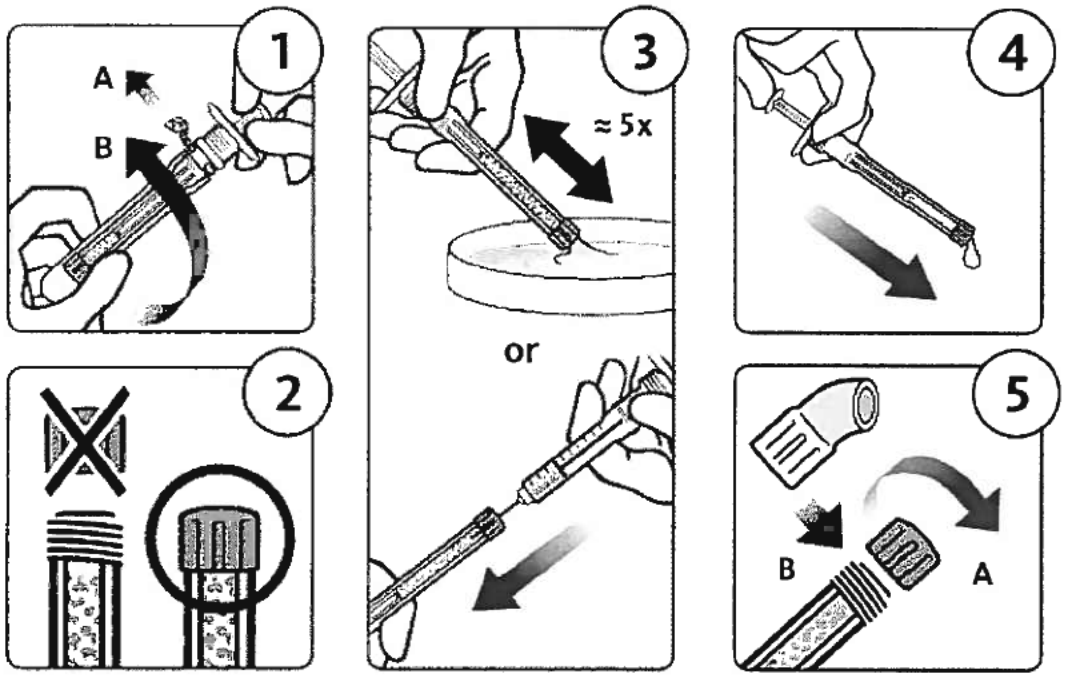
package insert: www.geistlich-na.com


1
A
B
2
3
≈ 5x
or
4
5
B
A

Geistlich Bio-Oss Collagen®
~~Natural~~ Bone Grafting Material

Geistlich Bio-Oss Collagen® is a sterile, biocompatible ~~natural~~ bone mineral plus collagen for bone grafting in periodontal, oral and maxillofacial surgery.

COMPOSITION:
Geistlich Bio-Oss Collagen® is a mixture of spongiosa (cancellous) bone granulate and 10% porcine collagen fibers in a block form, and is sterilized by γ -irradiation.

PROPERTIES / ACTION:
The anorganic bone matrix of Geistlich Bio-Oss Collagen® has physical and chemical properties comparable to the mineralized matrix of human bone. The collagen facilitates handling of the graft particles and acts to hold the Geistlich Bio-Oss® at the desired place. The consistency of this material readily allows it to take the shape of the defect. The graft is slowly resorbed and replaced by new bone.

INDICATIONS FOR USE:
Geistlich Bio-Oss Collagen® is recommended for:
- 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).

CONTRAINDICATIONS:
Geistlich Bio-Oss Collagen® should not be used in the presence of infected wounds.
Geistlich Bio-Oss Collagen® should not be used in patients with a known allergy to collagen.

DIRECTIONS FOR USE:
The general principles of sterile handling and patient medication must be followed when using Geistlich Bio-Oss Collagen®.
- The filling of periodontal defects with Geistlich Bio-Oss Collagen® requires successful treatment of the periodontal lesion (e.g., root planing, debridement of granulation tissue) prior to implantation. The defect should be covered with a membrane (e.g., Geistlich Bio-Gide®) for optimal tissue regeneration.
- After exposure of the bony defect with mucoperiosteal flap, all granulation tissue must be carefully removed.
- The material should be placed in direct contact with well vascularized, bleeding bone surfaces. Cortical bone should be mechanically perforated to facilitate ingrowth of new blood vessels and bone forming cells.
- Application: Geistlich Bio-Oss Collagen® may be cut to the required size with sterile tweezers and scissors, in dry form or after moistening with blood or physiological saline solution. The material is applied using sterile instruments (e.g., tweezers).
- If necessary, the material can be slightly molded in situ using a spatula or similar instrument.
- Overfilling of the defect should be avoided.
- It is advisable to cover Geistlich Bio-Oss® Collagen with a membrane barrier (e.g., Geistlich Bio-Gide®).
- When closing the wound, the soft tissue flap should completely cover the implanted Geistlich Bio-Oss Collagen®, and should be fixed by sutures.
- If primary wound closure cannot be achieved completely, further mobilization of the flap (incision through the periosteum) should be performed.
- A surgical dressing may be placed over the wound for one to two weeks.
- For improved bone formation in large osseous defects with one or two bony walls, Geistlich Bio-Oss Collagen® may be mixed with autogenous particulate spongiosa (cancellous) bone and marrow or covered with a cell occlusive membrane (e.g., Geistlich Bio-Gide®).

Geistlich Bio-Oss Collagen®
~~Natural~~ Bone Grafting Material

PRECAUTIONS:
Geistlich Bio-Oss Collagen® should only be used by trained dentists or oral surgeons.

In order to facilitate the formation of new bone, Geistlich Bio-Oss Collagen® should only be implanted in direct contact with well vascularized bony tissue (selective osteoplasty of adjacent cortical bone may be necessary). Drilling may be recommended to facilitate bleeding from cortical bone.

In larger defects a mixture of autogenous bone or bone marrow may improve the formation of new bone.
Generally, in augmented areas a mechanical loading or the insertion of endosseous implants (late implantation) should take place 4-6 months after the implantation of Geistlich Bio-Oss Collagen®. For sinus floor elevation with Geistlich Bio-Oss Collagen® 9-12 months should be allowed to assure osseointegration of titanium fixtures.

Geistlich Bio-Oss Collagen® should be used with special caution in patients with:
- Acute or chronic infection (osteomyelitis) at the surgical site
- Metabolic diseases (diabetes, hyperparathyroidism, osteomalacia)
- Osteoporosis
- Severe renal dysfunction, severe liver disease
- High dose corticosteroid therapy
- Vascular impairment at the implant site
- Autoimmune disease
- Radiotherapy
- Heavy smoking

Effect on pregnant or lactating women is not known.

ADVERSE REACTIONS:
Incompatibility reactions with Geistlich Bio-Oss Collagen® cannot be excluded. As Geistlich Bio-Oss Collagen® contains collagen, in very rare cases allergic reactions may occur. Possible complications which may occur with any surgery include swelling at the surgical site, flap sloughing, bleeding, local inflammation, bone loss, infection or pain.

STORAGE AND HANDLING:
If the sterile packaging is damaged or opened the product must not be used.
The contents of the blister package are designed for single use only. Discard any unused material after opening.
Resterilization is not possible.
Do not use after the expiration date.
Store at controlled room temperature 15°-25°C (59°-77°F) and in a dry place.

PRESENTATION: Geistlich Bio-Oss Collagen®:

Re-Order #:	Packaged:
20141	1 block 100 mg Geistlich Bio-Oss® spongiosa (cancellous) granules and 10% collagen
20142	1 block 250 mg Geistlich Bio-Oss® spongiosa (cancellous) granules and 10% collagen
20143	1 block 500 mg Geistlich Bio-Oss® spongiosa (cancellous) granules and 10% collagen

Geistlich Combi-Kit Collagen®

Re-Order #:	Packaged:
20146	1 block 100 mg Geistlich Bio-Oss® spongiosa (cancellous) granules and 10% collagen, and 1 Geistlich Bio-Gide® membrane, 16 x 22 mm

Distributed by:
Geistlich Pharma North America Inc.
Princeton, New Jersey 08540
1-(855) 799-5500
www.geistlich-na.com

Manufacturer:
Geistlich Pharma AG
CH-6110 Wolhusen
Switzerland

Made in Switzerland

CAUTION: Federal law restricts this device to sale by or on the order of a dentist or physician.
package insert: www.geistlich-na.com

IN0102
XXXXXX/XXXX

Geistlich Bio-Oss Collagen®
Bone Grafting Material

Geistlich Bio-Oss Collagen® is a sterile, biocompatible bone mineral plus collagen for bone grafting in periodontal, oral and maxillofacial surgery.

COMPOSITION:
Geistlich Bio-Oss Collagen® is a mixture of spongiosa (cancellous) bone granulate and 10% porcine collagen fibers in a block form, and is sterilized by γ -irradiation.

PROPERTIES / ACTION:
The anorganic bone matrix of Geistlich Bio-Oss Collagen® has physical and chemical properties comparable to the mineralized matrix of human bone. The collagen facilitates handling of the graft particles and acts to hold the Geistlich Bio-Oss® at the desired place. The consistency of this material readily allows it to take the shape of the defect. The graft is slowly resorbed and replaced by new bone.

INDICATIONS FOR USE:
Geistlich Bio-Oss Collagen® is recommended for:

- 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).

CONTRAINDICATIONS:
Geistlich Bio-Oss Collagen® should not be used in the presence of infected wounds.
Geistlich Bio-Oss Collagen® should not be used in patients with a known allergy to collagen.

DIRECTIONS FOR USE:
The general principles of sterile handling and patient medication must be followed when using Geistlich Bio-Oss Collagen®.

- The filling of periodontal defects with Geistlich Bio-Oss Collagen® requires successful treatment of the periodontal lesion (e.g., root planing, debridement of granulation tissue) prior to implantation. The defect should be covered with a membrane (e.g., Geistlich Bio-Gide®) for optimal tissue regeneration.
- After exposure of the bony defect with mucoperiosteal flap, all granulation tissue must be carefully removed.
- The material should be placed in direct contact with well vascularized, bleeding bone surfaces. Cortical bone should be mechanically perforated to facilitate ingrowth of new blood vessels and bone forming cells.
- Application: Geistlich Bio-Oss Collagen® may be cut to the required size with sterile tweezers and scissors, in dry form or after moistening with blood or physiological saline solution. The material is applied using sterile instruments (e.g., tweezers).
- If necessary, the material can be slightly molded in situ using a spatula or similar instrument.
- Overfilling of the defect should be avoided.
- It is advisable to cover Geistlich Bio-Oss® Collagen with a membrane barrier (e.g., Geistlich Bio-Gide®).
- When closing the wound, the soft tissue flap should completely cover the implanted Geistlich Bio-Oss Collagen®, and should be fixed by sutures.
- If primary wound closure cannot be achieved completely, further mobilization of the flap (incision through the periosteum) should be performed.
- A surgical dressing may be placed over the wound for one to two weeks.
- For improved bone formation in large osseous defects with one or two bony walls, Geistlich Bio-Oss Collagen® may be mixed with autogenous particulate spongiosa (cancellous) bone and marrow or covered with a cell occlusive membrane (e.g., Geistlich Bio-Gide®).

Geistlich Bio-Oss Collagen®
Bone Grafting Material

PRECAUTIONS:
Geistlich Bio-Oss Collagen® should only be used by trained dentists or oral surgeons.

In order to facilitate the formation of new bone, Geistlich Bio-Oss Collagen® should only be implanted in direct contact with well vascularized bony tissue (selective osteoplasty of adjacent cortical bone may be necessary). Drilling may be recommended to facilitate bleeding from cortical bone.

In larger defects a mixture of autogenous bone or bone marrow may improve the formation of new bone.
Generally, in augmented areas a mechanical loading or the insertion of endosseous implants (late implantation) should take place 4-6 months after the implantation of Geistlich Bio-Oss Collagen®. For sinus floor elevation with Geistlich Bio-Oss Collagen® 9-12 months should be allowed to assure osseointegration of titanium fixtures.

Geistlich Bio-Oss Collagen® should be used with special caution in patients with:
- Acute or chronic infection (osteomyelitis) at the surgical site
- Metabolic diseases (diabetes, hyperparathyroidism, osteomalacia)
- Osteoporosis
- Severe renal dysfunction, severe liver disease
- High dose corticosteroid therapy
- Vascular impairment at the implant site
- Autoimmune disease
- Radiotherapy
- Heavy smoking

Effect on pregnant or lactating women is not known.

ADVERSE REACTIONS:
Incompatibility reactions with Geistlich Bio-Oss Collagen® cannot be excluded. As Geistlich Bio-Oss Collagen® contains collagen, in very rare cases allergic reactions may occur. Possible complications which may occur with any surgery include swelling at the surgical site, flap sloughing, bleeding, local inflammation, bone loss, infection or pain.

STORAGE AND HANDLING:
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Resterilization is not possible.
Do not use after the expiration date.
Store at controlled room temperature 15°-25°C (59°-77°F) and in a dry place.

PRESENTATION: Geistlich Bio-Oss Collagen®:

Re-Order #:	Packaged:
20141	1 block 100 mg Geistlich Bio-Oss® spongiosa (cancellous) granules and 10% collagen
20142	1 block 250 mg Geistlich Bio-Oss® spongiosa (cancellous) granules and 10% collagen
20143	1 block 500 mg Geistlich Bio-Oss® spongiosa (cancellous) granules and 10% collagen

Geistlich Combi-Kit Collagen®

Re-Order #:	Packaged:
20146	1 block 100 mg Geistlich Bio-Oss® spongiosa (cancellous) granules and 10% collagen, and 1 Geistlich Bio-Gide® membrane, 16 x 22 mm

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www.geistlich-na.com

Manufacturer:
Geistlich Pharma AG
CH-6110 Wolhusen
Switzerland

Made in Switzerland

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package insert: www.geistlich-na.com

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APPENDIX F

Distributed by:
Geistlich Pharma
North America Inc.
Princeton, New Jersey 08540
1-(855) 799-5500
www.geistlich-na.com

Geistlich Bio-Oss®

bone grafting material
small particles 0.25–1.0 mm
cancellous granules 0.25 g ≈ 0.5 cc

0.25 g

935111/1102

Caution: Federal law restricts this device to sale by or on the order of a dentist or physican. Store at room temperature 15–25°C (59–77°F) in a dry place.

Contents: sterile cancellous granules
Particle size 0.25–1.0 mm, 0.25 g
For single use only.

LOT

EXP.

Geistlich
Bio-Oss® 0.25 g
Sterile cancellous granules
0.25–1.0 mm
For single use only.
Re-Order No. 20111
Reference 1

LOT

EXP.

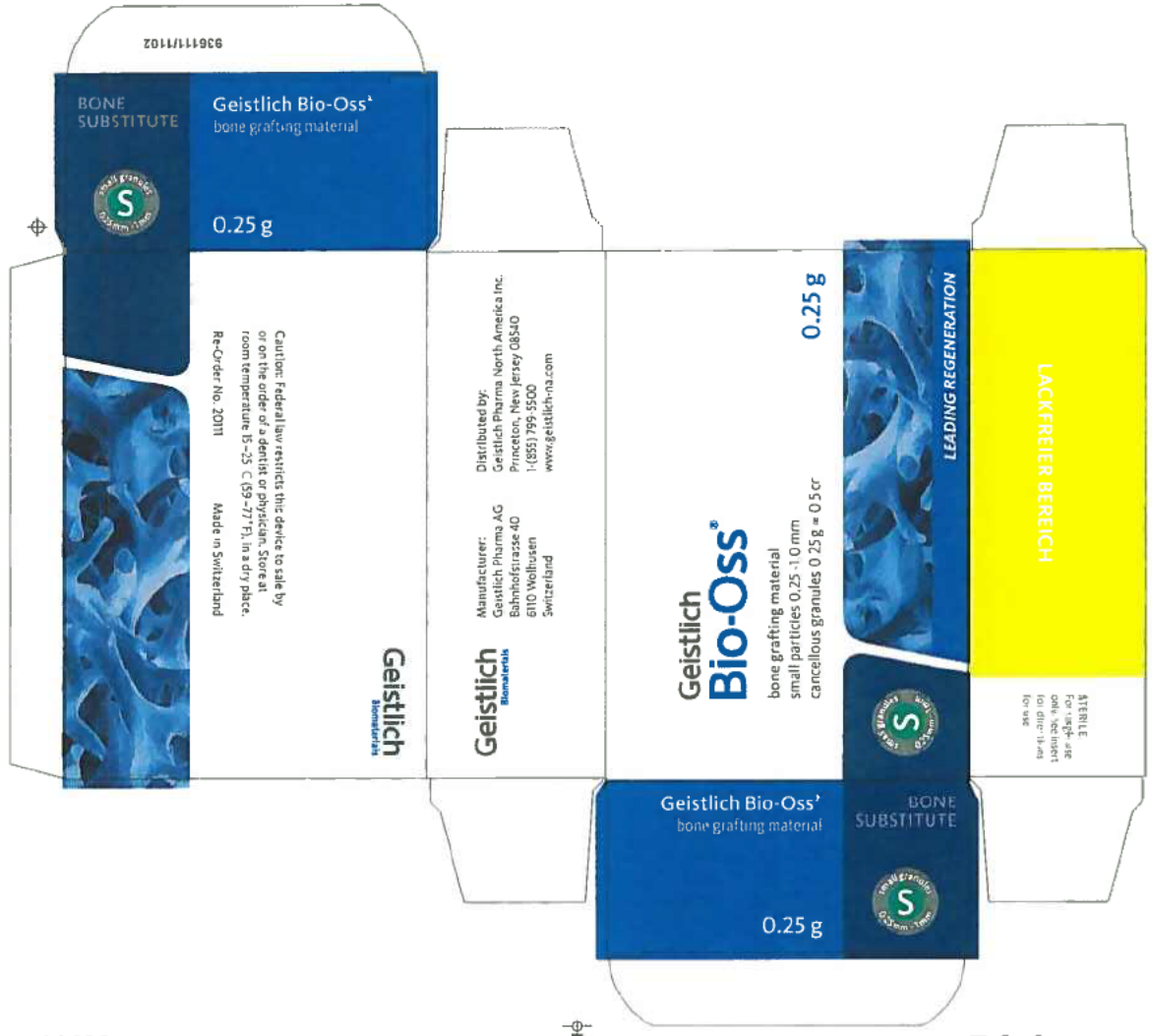
LACKFREIER BEREICH

Geistlich
Bio-Oss® 0.25 g
Sterile cancellous granules
0.25–1.0 mm
For single use only.
Re-Order No. 20111
Reference 2

LOT

EXP.

az11400



az11400
73 x 36 x 106 mm

Edelmann
Stanzvorlage

DScript stanzform

Distributed by:
Geistlich Pharma
North America Inc.
Princeton, New Jersey 08540
1-(855) 799-5500
www.geistlich-na.com

Geistlich Bio-Oss®

bone grafting material
small particles 0.25–1.0 mm
cancellous granules 0.5 g ≈ 1 cc

0.5 g

935112/1102

Caution: Federal law restricts this device to sale by or on the order of a dentist or physican. Store at room temperature 15–25°C (59–77°F) in a dry place.

Contents: sterile cancellous granules
Particle size 0.25–1.0 mm, 0.5 g
For single use only.

LOT

EXP.

Geistlich
Bio-Oss® 0.5 g
Sterile cancellous granules
0.25–1.0 mm
For single use only.
Re-Order No. 20112
Reference 1

LOT

EXP.

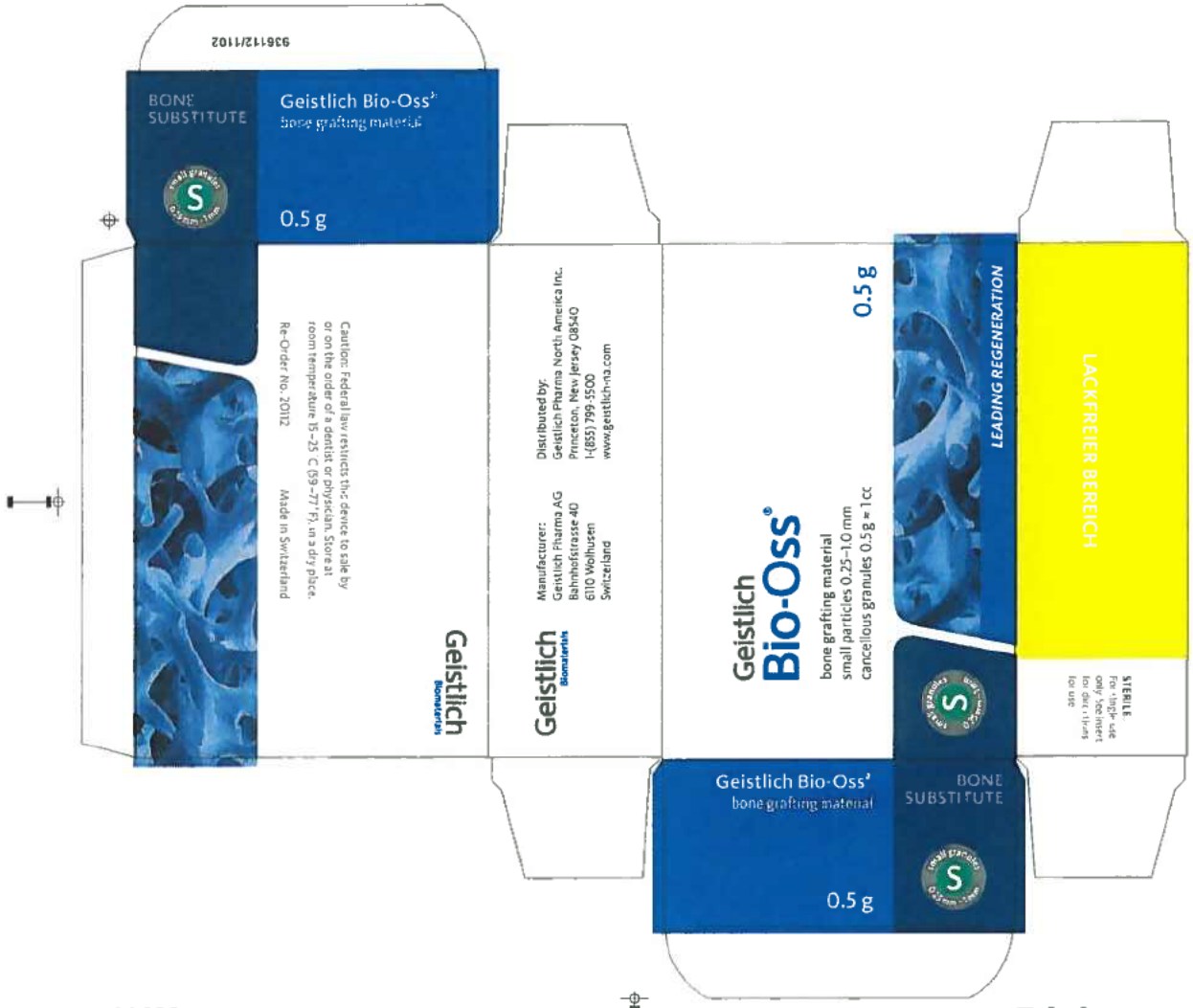
LACKFREIER BEREICH

Geistlich
Bio-Oss® 0.5 g
Sterile cancellous granules
0.25–1.0 mm
For single use only.
Re-Order No. 20112
Reference 2

LOT

EXP.

az11400



az11400
73 x 36 x 106 mm

Edelmann
Stanzvorlage

DScript stanzform

Distributed by:
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North America Inc.
Princeton, New Jersey 08540
1-(855) 799-5500
www.geistlich-na.com

Geistlich Bio-Oss®

bone grafting material
large particles 1.0–2.0 mm
cancellous granules 0.5 g ≈ 1.5 cc

0.5 g

Caution: Federal law restricts this device to sale by or on the order of a dentist or physican. Store at room temperature 15–25°C (59–77°F) in a dry place.

Contents: sterile cancellous granules
Particle size 1.0–2.0 mm, 0.5 g
For single use only.

935121/1102

LOT

EXP.

Geistlich
Bio-Oss® 0.5 g
Sterile cancellous granules
1.0–2.0 mm
For single use only.
Re-Order No. 20121
Reference 1

LOT

EXP.

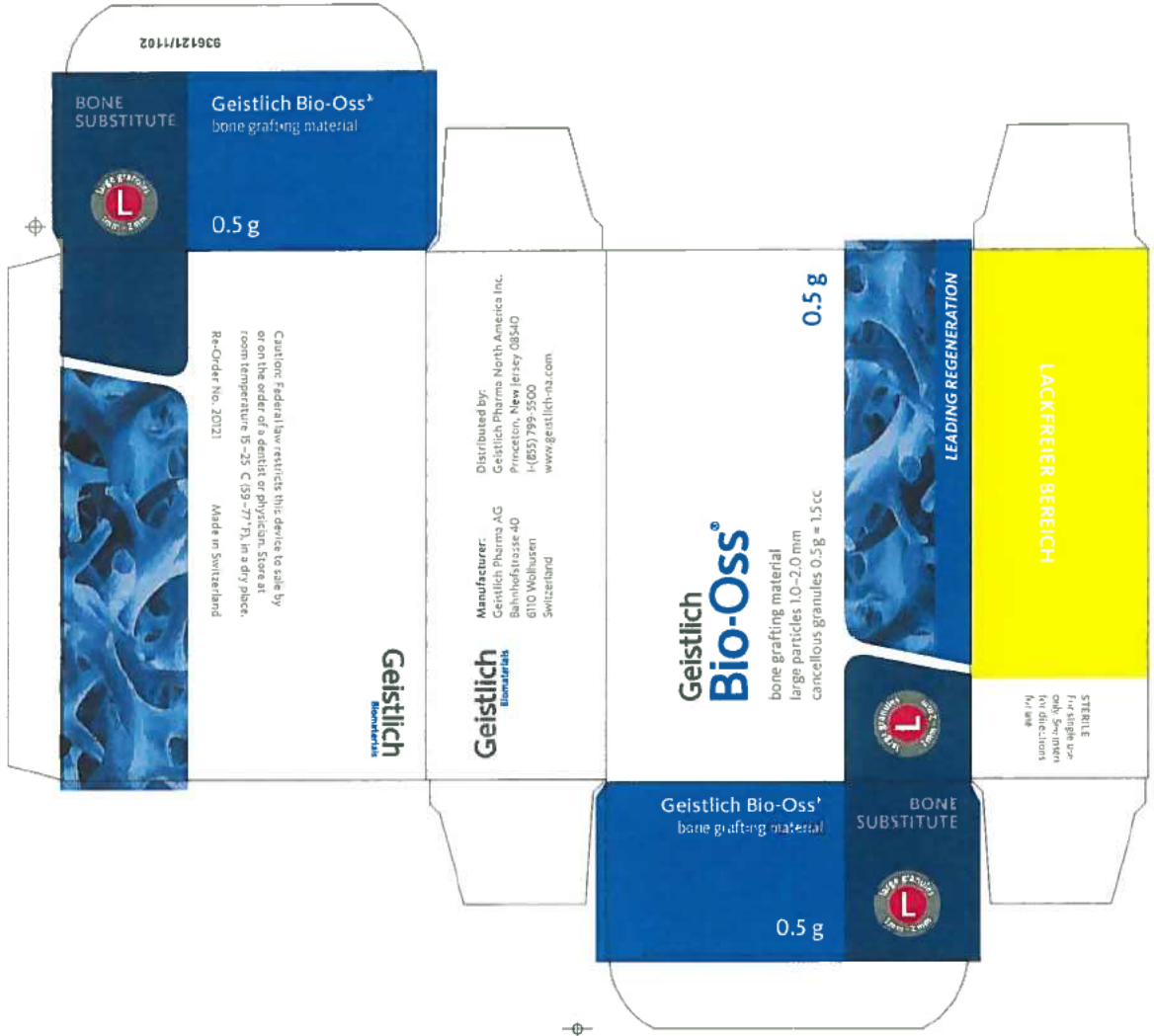
LACKFREIER BEREICH

Geistlich
Bio-Oss® 0.5 g
Sterile cancellous granules
1.0–2.0 mm
For single use only.
Re-Order No. 20121
Reference 2

LOT

EXP.

az11400



az11400
73 x 36 x 106 mm

Edelmann
Stanzvorlage

DScript stanzform

Distributed by:
Geistlich Pharma
North America Inc.
Princeton, New Jersey 08540
1-(855) 799-5500
www.geistlich-na.com

Geistlich Bio-Oss®

bone grafting material
small particles 0.25–1.0 mm
cancellous granules 2 g ≈ 4 cc

2 g

935113/1102

Caution: Federal law restricts this device to sale by or on the order of a dentist or physican. Store at room temperature 15–25°C (59–77°F) in a dry place.

Contents: sterile cancellous granules
Particle size 0.25–1.0 mm, 2 g
For single use only.

LOT

EXP.

Geistlich
Bio-Oss® 2 g
Sterile cancellous granules
0.25–1.0 mm
For single use only.
Re-Order No. 20113
Reference 1

LOT

EXP.

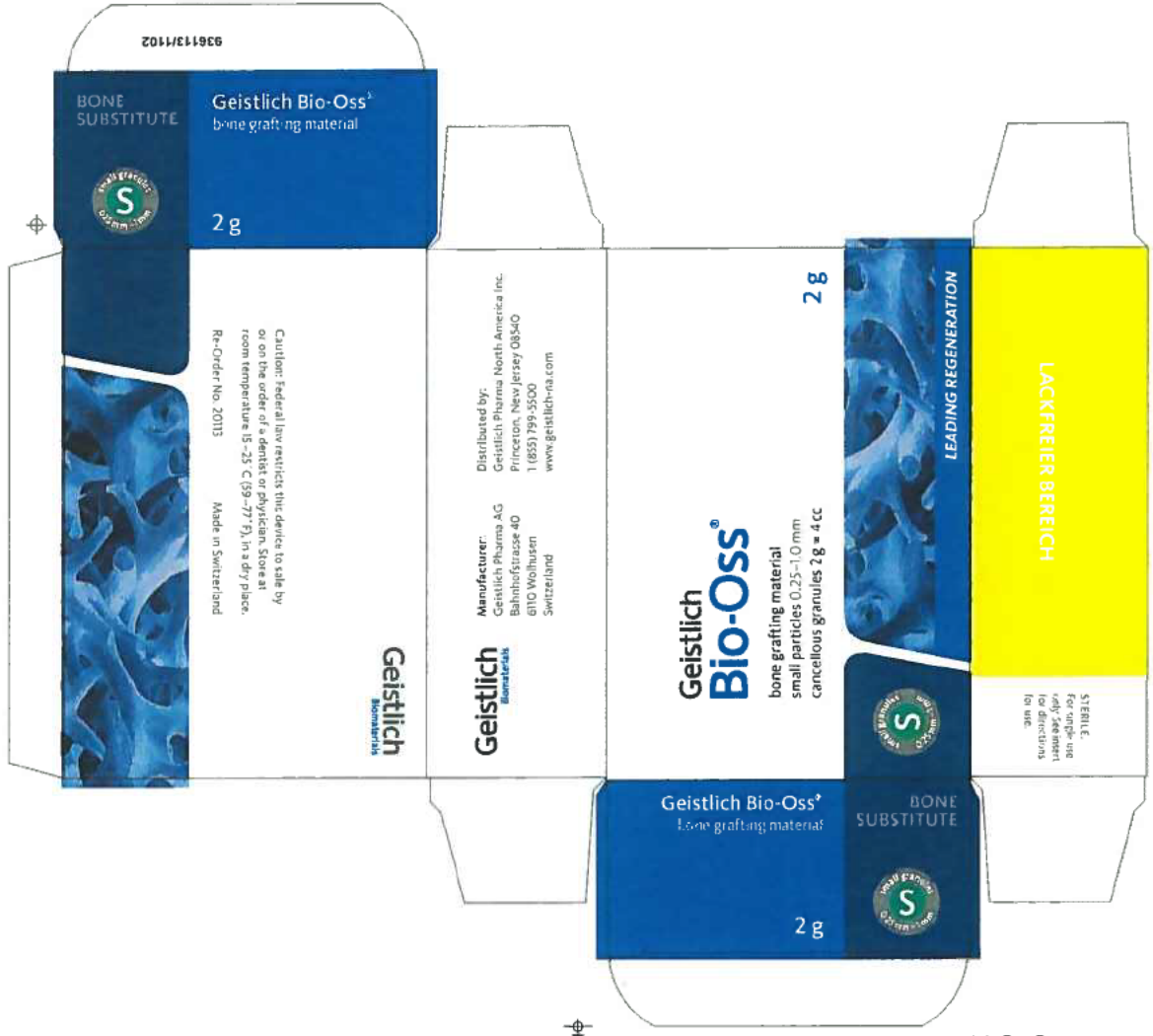
LACKFREIER BEREICH

Geistlich
Bio-Oss® 2 g
Sterile cancellous granules
0.25–1.0 mm
For single use only.
Re-Order No. 20113
Reference 2

LOT

EXP.

az11400



az11400
73 x 36 x 106 mm

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Geistlich Bio-Oss®

bone grafting material
large particles 1.0–2.0 mm
cancellous granules 2 g ≈ 6 cc

2 g

935122/1102

Caution: Federal law restricts this device to sale by or on the order of a dentist or physican. Store at room temperature 15–25°C (59–77°F) in a dry place.

Contents: sterile cancellous granules
Particle size 1.0–2.0 mm, 2 g
For single use only.

LOT

EXP.

Geistlich
Bio-Oss® 2 g
Sterile cancellous granules
1.0–2.0 mm
For single use only.
Re-Order No. 20122
Reference 1

LOT

EXP.

LACKFREIER BEREICH

Geistlich
Bio-Oss® 2 g
Sterile cancellous granules
1.0–2.0 mm
For single use only.
Re-Order No. 20122
Reference 2

LOT

EXP.

az11400

936122/1102

BONE SUBSTITUTE

Geistlich Bio-Oss®
bone grafting material

2 g

Geistlich Biomaterials

Caution: Federal law restricts this device to sale by or on the order of a dentist or physician. Store at room temperature 15–25°C (59–77°F), in a dry place.

Re-Order No. 20122 Made in Switzerland

Geistlich Biomaterials

Manufacturer:
Geistlich Pharma AG
Bahnhofstrasse 40
6110 Wolhusen
Switzerland

Distributed by:
Geistlich Pharma North America Inc.
Princeton, New Jersey 08540
1-(855) 799-5500
www.geistlich-na.com

Geistlich
Bio-Oss®

bone grafting material
large particles 1.0–2.0 mm
cancellous granules 2 g ≈ 6 cc

2 g

LEADING REGENERATION

Geistlich Bio-Oss®
bone grafting material

2 g

BONE SUBSTITUTE

LACKFREIER BEREICH

STERILE
For single use only. See insert for directions for use

Edelmann
Stanzvorlage

az11400
73 x 36 x 106 mm

DScript stanzform

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North America Inc.
Princeton, New Jersey 08540
1-(855) 799-5500
www.geistlich-na.com

Geistlich Bio-Oss®

bone grafting material
small particles 0.25–1.0 mm
cancellous granules 5 g ≈ 10 cc

5 g

935114/1102

Caution: Federal law restricts this device to sale by or on the order of a dentist or physican. Store at room temperature 15–25°C (59–77°F) in a dry place.

Contents: sterile cancellous granules
Particle size 0.25–1.0 mm, 5 g
For single use only.

LOT

EXP.

Geistlich
Bio-Oss® 5 g
Sterile cancellous granules
0.25–1.0 mm
For single use only.
Re-Order No. 20114
Reference 1

LOT

EXP.

LACKFREIER BEREICH

Geistlich
Bio-Oss® 5 g
Sterile cancellous granules
0.25–1.0 mm
For single use only.
Re-Order No. 20114
Reference 2

LOT

EXP.

az11400

az11400
73 x 36 x 106 mm

Edelmann
Stanzvorlage

DScript stanzform

Distributed by:
Geistlich Pharma
North America Inc.
Princeton, New Jersey 08540
1-(855) 799-5500
www.geistlich-na.com

Geistlich Bio-Oss® Block

bone grafting material
1 preformed block 1 x 1 x 2 cm

1 x 1 x 2 cm

935131/1102

Caution: Federal law restricts this device to sale by or on the order of a dentist or physican. Store at room temperature 15–25°C (59–77°F) in a dry place.

Contents:
1 sterile preformed block 1 x 1 x 2 cm
For single use only.

LOT

EXP.

Geistlich
Bio-Oss® Block

1 sterile preformed block
1 x 1 x 2 cm
For single use only.
Re-Order No. 20131
Reference 1

LOT

EXP.

LACKFREIER BEREICH

Geistlich
Bio-Oss® Block

1 sterile preformed block
1 x 1 x 2 cm
For single use only.
Re-Order No. 20131
Reference 2

LOT

EXP.

az11399

936131/1102

BONE SUBSTITUTE

Geistlich Bio-Oss® Block

bone grafting material

1 x 1 x 2 cm

Geistlich Biomaterials

Caution: Federal law restricts this device to sale by or on the order of a dentist or physician. Store at room temperature 15–25 °C (59–77 °F), in a dry place.

Re Order No. 20131

Made in Switzerland

Geistlich Biomaterials

Manufacturer
Geistlich Pharma AG
Bahnhofstrasse 40
6110 Wolhusen
Switzerland

Distributed by:
Geistlich Pharma North America Inc.
Princeton, New Jersey 08540
1-(855) 799-5500
www.geistlich-na.com

Geistlich

Bio-Oss® Block

bone grafting material
1 preformed block 1 x 1 x 2 cm

1 x 1 x 2 cm

LEADING REGENERATION

LACKFREIER BEREICH

STERILE.
For single use only. See insert for directions for use.

BONE SUBSTITUTE

Geistlich Bio-Oss® Block

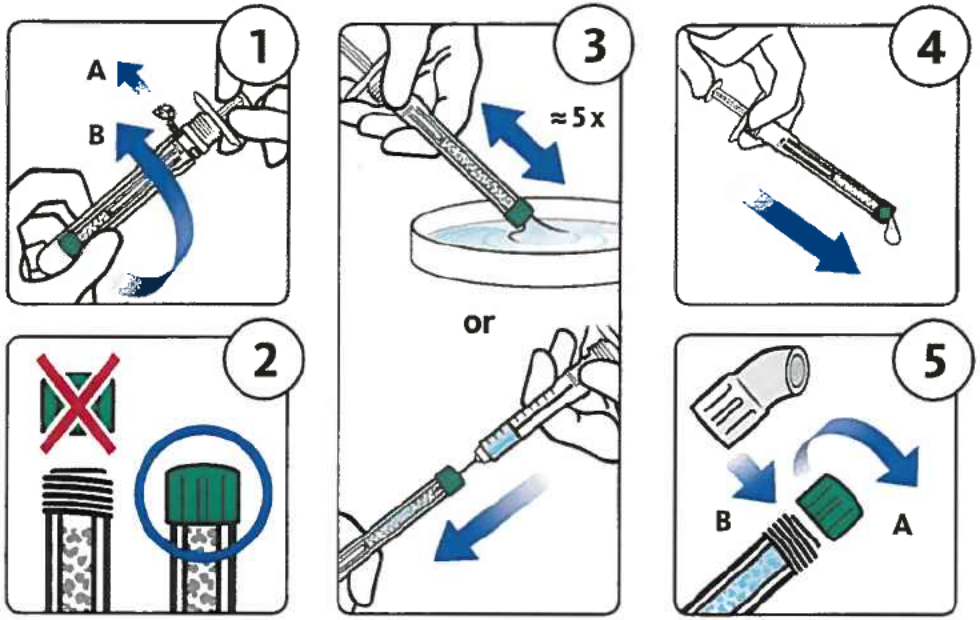
bone grafting material

1 x 1 x 2 cm

az11399
73 x 28 x 106 mm

Edelmann
Stanzvorlage

DScript stanzform



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www.geistlich-na.com

Geistlich Bio-Oss Pen®

bone grafting material
small particles 0.25 mm – 1 mm
cancellous granules 0.25 g ≈ 0.5 cc

0.25 g

935115/1110

Caution: Federal law restricts this device to sale by or on the order of a dentist or physican. Store at room temperature 15–25°C (59–77°F) in a dry place.

Contents: sterile cancellous granules
Particle size 0.25 mm – 1 mm, 0.25 g
For single use only.

LOT
EXP.

Geistlich
Bio-Oss Pen®
Sterile cancellous granules
0.25 mm – 1 mm, 0.25 g
For single use only.
Re-Order No. 20115
Reference 1

LOT
EXP.

LACKFREIER BEREICH

Geistlich
Bio-Oss Pen®
Sterile cancellous granule
0.25 mm – 1 mm, 0.25 g
For single use only.
Re-Order No. 20115
Reference 2

LOT
EXP.

Geistlich
Bio-Oss Pen®

bone grafting material
small particles 0.25 mm – 1 mm
cancellous granules 0.25 g ≈ 0.5 cc

0.25 g

LACKFREIER BEREICH

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www.geistlich-na.com

Manufacturer:
Geistlich Pharma AG
Bahnhofstrasse 40
6110 Wolhusen
Switzerland

Geistlich
Biomaterials

Geistlich
Bio-Oss Pen®

STERILE. For single use only.
See insert for directions for use.

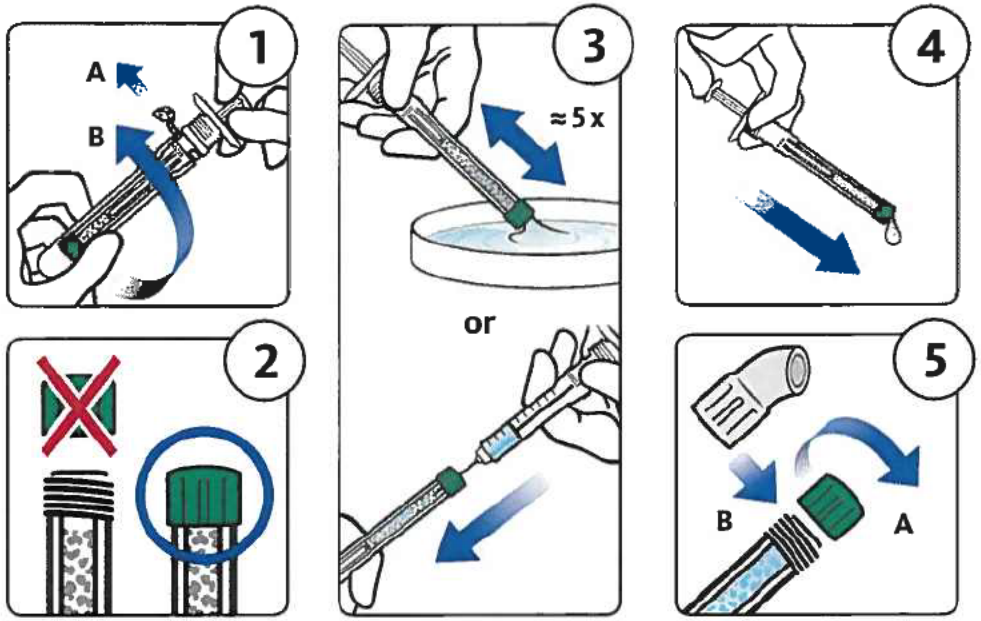
Patent pending

Caution: Federal law restricts this device to sale by or on the order of a dentist or physician. Store at room temperature 15–25° C (59–77° F), in a dry place.

Re Order No. 20115

Made in Switzerland

936115/1110



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North America Inc.
Princeton, New Jersey 08540
1-(855) 799-5500
www.geistlich-na.com

Geistlich Bio-Oss Pen®

bone grafting material
small particles 0.25 mm – 1 mm
cancellous granules 0.5 g ≈ 1 cc

0.5 g

935116/1110

Caution: Federal law restricts this device to sale by or on the order of a dentist or physican. Store at room temperature 15–25°C (59–77°F) in a dry place.

Contents: sterile cancellous granules
Particle size 0.25 mm – 1 mm, 0.5 g
For single use only.

LOT
EXP.

Geistlich
Bio-Oss Pen®
Sterile cancellous granules
0.25 mm – 1 mm, 0.5 g
For single use only.
Re-Order No. 20116
Reference 1

LOT
EXP.

LACKFREIER BEREICH

Geistlich
Bio-Oss Pen®
Sterile cancellous granule
0.25 mm – 1 mm, 0.5 g
For single use only.
Re-Order No. 20116
Reference 2

LOT
EXP.

Geistlich Bio-Oss Pen®
bone grafting material
0.5 g

BONE SUBSTITUTE

Geistlich
Bio-Oss Pen®

bone grafting material
small particles 0.25 mm – 1 mm
cancellous granules 0.5 g ≈ 1 cc

0.5 g

LEADING REGENERATION

LACKFREIER BEREICH

Geistlich Bio-Oss Pen®
bone grafting material
0.5 g

BONE SUBSTITUTE

Manufacturer:
Geistlich Pharma AG
Bahnhofstrasse 40
6110 Wolhusen
Switzerland

Distributed by:
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Princeton, New Jersey 08540
1 (855) 799-5500
www.geistlich-na.com

Geistlich
Biomaterials

Geistlich
Bio-Oss Pen®

STERILE. For single use only.
See insert for directions for use

Patent pending

Caution: Federal law restricts this device to sale by or on the order of a dentist or physician. Store at room temperature 15 -25°C (59 -77°F), in a dry place

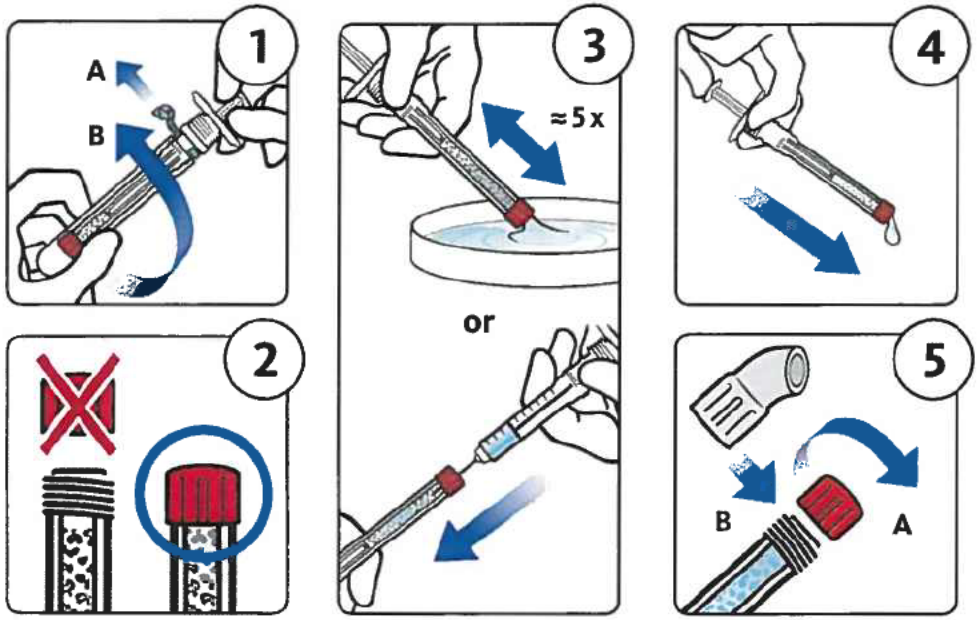
Made in Switzerland

Re Order No. 20116

Geistlich Bio-Oss Pen®
bone grafting material
0.5 g

BONE SUBSTITUTE

936116/1110



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www.geistlich-na.com

Geistlich Bio-Oss Pen®

bone grafting material
large particles 1 mm – 2 mm
cancellous granules 0.5 g ≈ 1.5 cc

0.5 g

935126/1110

Caution: Federal law restricts this device to sale by or on the order of a dentist or physican. Store at room temperature 15–25°C (59–77°F) in a dry place.

Contents: sterile cancellous granules
Particle size 1 mm – 2 mm, 0.5 g
For single use only.

LOT
EXP.

Geistlich Bio-Oss Pen®
Sterile cancellous granules
1 mm – 2 mm, 0.5 g
For single use only.
Re-Order No. 20126
Reference 1

LOT
EXP.

LACKFREIER BEREICH

Geistlich Bio-Oss Pen®
Sterile cancellous granule
1 mm – 2 mm, 0.5 g
For single use only.
Re-Order No. 20126
Reference 2

LOT
EXP.

Geistlich
Bio-Oss Pen®

bone grafting material
large particles 1 mm - 2 mm
cancellous granules 0.5 g = 1.5 cc

0.5 g

LEADING REGENERATION

LACKFREIER BEREICH

Geistlich Bio-Oss Pen®
bone grafting material
0.5 g

BONE SUBSTITUTE

Manufacturer:
Geistlich Pharma AG
Bahnhofstrasse 40
6110 Wolhusen
Switzerland

Distributed by:
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Princeton, New Jersey 08540
1 (855) 799-5500
www.geistlich-na.com

Geistlich
Biomaterials

Geistlich
Bio-Oss Pen®

Caution: Federal law restricts this device to sale by or on the order of a dentist or physician. Store at room temperature 15 - 25°C (59-77°F), in a dry place.

Re Order No. 20125

Made in Switzerland

STERILE For single use only
See insert for directions for use.

Patent pending

Geistlich Bio-Oss Pen®
bone grafting material
0.5 g

BONE SUBSTITUTE

9361261/1110

Distributed by:
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North America Inc.
Princeton, New Jersey 08540
1-(855) 799-5500
www.geistlich-na.com

Geistlich Bio-Oss Collagen®

bone grafting material
1 preformed block 100 mg

100 mg

935141/1102

Caution: Federal law restricts this device to sale by or on the order of a dentist or physican. Store at room temperature 15–25°C (59–77°F) in a dry place.

Contents:
1 sterile preformed block 100 mg cancellous granules + collagen.
For single use only.

LOT

EXP.

Geistlich Bio-Oss Collagen®

1 preformed block 100 mg
Sterile. For single use only.
Re-Order No. 20141
Reference 1

LOT

EXP.

LACKFREIER BEREICH

Geistlich Bio-Oss Collagen®

1 preformed block 100 mg
Sterile. For single use only.
Re-Order No. 20141
Reference 2

LOT

EXP.

az11399

936141/1102

BONE SUBSTITUTE

Geistlich Bio-Oss Collagen®
bone grafting material
100 mg

Geistlich Biomaterials

Caution: Federal law restricts this device to sale by or on the order of a dentist or physician. Store at room temperature 15–25 °C (59–77 °F), in a dry place

Re-Order No. 20141

Made in Switzerland

Geistlich Biomaterials

Manufacturer:
Geistlich Pharma AG
Bahnhofstrasse 40
6110 Wolhusen
Switzerland

Distributed by:
Geistlich Pharma North America Inc.
Princeton, New Jersey 08540
1-(855) 799-5500
www.geistlich-na.com

Geistlich
Bio-Oss Collagen®

bone grafting material
1 preformed block 100 mg

100 mg

LEADING REGENERATION

Geistlich Bio-Oss Collagen®
bone grafting material
100 mg

BONE SUBSTITUTE

LACKFREIER BEREICH

STERILE.
For single use only. Sterilized for direct from the use.

az11399
73 x 28 x 106 mm

Edelmann
Stanzvorlage

DScript stanzform

Distributed by:
Geistlich Pharma
North America Inc.
Princeton, New Jersey 08540
1-(855) 799-5500
www.geistlich-na.com

Geistlich Bio-Oss Collagen®

bone grafting material
1 preformed block 250 mg

250 mg

935142/1102

Caution: Federal law restricts this device to sale by or on the order of a dentist or physican. Store at room temperature 15–25°C (59–77°F) in a dry place.

Contents:
1 sterile preformed block 250 mg cancellous granules + collagen.
For single use only.

LOT

EXP.

Geistlich
Bio-Oss Collagen®

1 preformed block 250 mg
Sterile. For single use only.
Re-Order No. 20142
Reference 1

LOT

EXP.

LACKFREIER BEREICH

Geistlich
Bio-Oss Collagen®

1 preformed block 250 mg
Sterile. For single use only.
Re-Order No. 20142
Reference 2

LOT

EXP.

az11399

936142/11102

BONE SUBSTITUTE

Geistlich Bio-Oss Collagen®
bone grafting material
250 mg

Geistlich Biomaterials

Caution: Federal law restricts this device to sale by or on the order of a dentist or physician. Store at room temperature 15–25 °C (59–77 °F). In a dry place.

Re-Order No. 20142 Made in Switzerland

Geistlich Biomaterials

Manufacturer:
Geistlich Pharma AG
Bahnhofstrasse 40
6110 Wolhusen
Switzerland

Distributed by:
Geistlich Pharma North America Inc.
Princeton, New Jersey 08540
1-(855) 799-5500
www.geistlich-na.com

Geistlich
Bio-Oss Collagen®

bone grafting material
1 preformed block 250 mg

250 mg

LEADING REGENERATION

STERILE
For single use only. Sterilized for disclaimers for use

LACKFREIER BEREICH

Geistlich Bio-Oss Collagen®
bone grafting material
250 mg

BONE SUBSTITUTE

az11399
73 x 28 x 106 mm

Edelmann
Stanzvorlage

DScript stanzform

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North America Inc.
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www.geistlich-na.com

Geistlich Bio-Oss Collagen®

bone grafting material
1 preformed block 500 mg

500 mg

Caution: Federal law restricts this device to sale by or on the order of a dentist or physican. Store at room temperature 15–25°C (59–77°F) in a dry place.

Contents:
1 sterile preformed block 500 mg cancellous granules + collagen.
For single use only.

935143/1102

LOT

EXP.

Geistlich Bio-Oss Collagen®

1 preformed block 500 mg
Sterile. For single use only.
Re-Order No. 20143
Reference 1

LOT

EXP.

LACKFREIER BEREICH

Geistlich Bio-Oss Collagen®

1 preformed block 500 mg
Sterile. For single use only.
Re-Order No. 20143
Reference 2

LOT

EXP.

az11399

936143/1102

BONE SUBSTITUTE

Geistlich Bio-Oss Collagen®
bone grafting material
500 mg

Geistlich Biomaterials

Caution: Federal law restricts this device to sale by or on the order of a dentist or physician. Store at room temperature 15–25°C (59–77°F), in a dry place.

Re-Order No. 20143

Made in Switzerland

Geistlich Biomaterials

Manufacturer:
Geistlich Pharma AG
Bahnhofstrasse 40
6110 Wolhusen
Switzerland

Distributed by:
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1-(855) 799-5500
www.geistlich-na.com

Geistlich
Bio-Oss Collagen®

bone grafting material
1 preformed block 500 mg

500 mg

LEADING REGENERATION

LACKFREIER BEREICH

STERILE
For single use
only. See insert
for directions
for use

Geistlich Bio-Oss Collagen®
bone grafting material
500 mg

BONE SUBSTITUTE

Edelmann
Stanzvorlage

az11399
73 x 28 x 106 mm

Script
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Distributed by:
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www.geistlich-na.com

Geistlich Combi-Kit Collagen

resorbable bilayer collagen membrane
1 membrane 16 x 22 mm
bone grafting material
1 preformed block 100 mg

16 x 22 mm
100 mg

Caution: Federal law restricts this device to sale by or on the order of a dentist or physican. Store at room temperature 15–25°C (59–77°F) in a dry place.

Contents: 1 sterile membrane 16 x 22 mm, 1 sterile preformed block 100 mg cancellous granules + collagen For single use only.

US patent: No. 5,837,278

935146/1102

LOT

EXP.

Geistlich
Combi-Kit Collagen

1 membrane 16 x 22 mm
1 preformed block 100 mg
Sterile. For single use only.
Re-Order No. 20146
Reference 1

LOT

EXP.

LACKFREIER BEREICH

Geistlich
Combi-Kit Collagen

1 membrane 16 x 22 mm
1 preformed block 100 mg
Sterile. For single use only.
Re-Order No. 20146
Reference 2

LOT

EXP.

az11399

936146/1102

MEMBRANE
BONE
SUBSTITUTE

Geistlich
Combi-Kit Collagen
resorbable bilayer collagen
membrane 16 x 22 mm
bone grafting
material 100 mg

Geistlich
Combi-Kit Collagen

1 Geistlich Bio-Gide® 16 x 22 mm
1 Geistlich Bio-Oss Collagen® 100 mg

LEADING REGENERATION

LACKFREIER BEREICH

STERILE
For single use
only. See inserts
for directions
for use

Geistlich
Biomaterials

Manufacturer:
Geistlich Pharma AG
Bahnhofstrasse 40
6110 Wolhusen
Switzerland

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Geistlich
Biomaterials

Caution: Federal law restricts this device to sale by
or on the order of a dentist or physician. Store at
room temperature 15–25°C (59–77 °F), in a dry place.
Re Order No. 20146
US Patent No. 5,837,278

Made in Switzerland

MEMBRANE
BONE
SUBSTITUTE

Geistlich
Combi-Kit Collagen
resorbable bilayer collagen
membrane 16 x 22 mm
bone grafting
material 100 mg

az11399
73 x 28 x 106 mm

Edelmann
Stanzvorlage

Script stanzform

Distributed by:
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North America Inc.
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Geistlich Perio-System Combi-Pack

resorbable bilayer collagen membrane
1 membrane 16 x 22 mm
bone grafting material
1 preformed block 100 mg

16 x 22 mm
100 mg

Caution: Federal law restricts this device to sale by or on the order of a dentist or physican. Store at room temperature 15–25°C (59–77°F) in a dry place.

Contents: 1 sterile membrane 16 x 22 mm, 1 sterile preformed block 100 mg cancellous granules + collagen For single use only.

US patent: No. 5,837,278

935147/1102

Geistlich Perio-System Combi-Pack
1 membrane 16 mm x 22 mm
1 preformed block 100 mg
Sterile. For single use only.
Re-Order No. 20147
Reference 1

Geistlich Perio-System Combi-Pack
1 membrane 16 mm x 22 mm
1 preformed block 100 mg
Sterile. For single use only.
Re-Order No. 20147
Reference 2

LOT
EXP.

LOT
EXP.

LACKFREIER BEREICH

LOT
EXP.

az11399

936147/1102

MEMBRANE
BONE
SUBSTITUTE

Geistlich Perio System
Combi-Pack
resorbable bilayer collagen
membrane 16 x 22 mm
bone grafting
material 100 mg

Geistlich
Biomaterials

Caution: Federal law restricts this device to sale by
or on the order of a dentist or physician. Store at
room temperature 15–25 °C (59–77 °F), in a dry place

Re-Order No. 20147

US Patent No. 5,837,278

Made in Switzerland

Geistlich
Biomaterials

Manufacturer:
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Bahnhofstrasse 40
6110 Wolhusen
Switzerland

Distributed by:
Geistlich Pharma North America Inc.
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www.geistlich-na.com

Geistlich
Perio-System Combi-Pack

1 Geistlich Bio Gide® Perio 16 mm x 22 mm
1 Geistlich Bio-Oss Collagen® 100 mg

Geistlich Perio System
Combi-Pack
resorbable bilayer collagen
membrane 16 x 22 mm
bone grafting
material 100 mg

MEMBRANE
BONE
SUBSTITUTE

LACKFREIER BEREICH

STERILE
For single use
only. Sterilisation
for dentalions
for use

az11399
73 x 28 x 106 mm

Edelmann
Stanzvorlage

stanzform

Dscript

APPENDIX G

Geistlich
Pharma

To whom it may concern

Confirmatory Statement in response to AIK122894

Geistlich Pharma AG acknowledges that Geistlich Bio-Oss and Geistlich Bio-Oss Collagen will not be promoted as being "natural", or as superior to other legally marketed bone void fillers unless otherwise permissible under the Federal Food, Drug, and Cosmetic Act.

Geistlich Pharma AG

1/31/2013
Date / Signature

Mario Mucha
COO

1/31/13
Date / Signature

Michael Egerszegi
Group Manager International Marketing

Geistlich Pharma AG | Bahnhofstrasse 40 | CH-6110 Wolhusen
Phone + 41 41 492 55 55 | Fax + 41 41 492 55 09 | www.geistlich.com | info@geistlich.ch