K120601

MAY 2 4 2012

**510(k) Summary**

## GEISTLICH BIO-OSS PEN®

### SPONSOR

Geistlich Pharma AG
Bahnhofstrasse 40
CH-6110 Wolhusen
Switzerland

Contact Person: Daniel Kracov, Arnold & Porter, LLP
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Phone: (202)942-5120
Date Prepared: April 25, 2012

### DEVICE NAME

Proprietary Name: Geistlich Bio-Oss Pen®

Common/Usual Names: Natural Bone Grafting Material

Classification Name: Bone grafting material, animal source (NPM)

### PREDICATE DEVICES

Geistlich Bio-Oss® (K112572, K033815)
RTR Syringe (K063634)

### DEVICE DESCRIPTION

Geistlich Bio-Oss® spongiosa (cancellous) granules are natural non-antigenic porous bone mineral matrices. They are 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. Geistlich Bio-Oss® granules are available in small particles (0.25 – 1.0 mm) and large particles (1.0 – 2.0 mm).

A polymer syringe-like applicator has been designed to deliver the granules more precisely to the intended treatment site without having to use other sterile instruments. The Geistlich Bio-Oss® granules can be wetted with either the patient's blood or sterile physiological saline solution by injection directly through the filter cap of the syringe-like applicator Geistlich Bio-Oss Pen®. After the filter cap is replaced with the angle cap

K120601

applicator the granules can be applied directly to the surgical site.

During the manufacturing process of Geistlich Bio-Oss Pen® the granules are placed in ~~a~~ the polymer syringe-like applicator, packaged in a polyethylene terephthalate tray and covered with a Tyvek lid, sealed and then sterilized by gamma irradiation. The sterilized device is placed in the protective packaging (outer box) along with its Instructions for Use, and is intended for single-use only.

Geistlich Bio-Oss Pen® will be available to the United States market in four versions: filled with 0.25 g, 0.5 g, or 0.7 g of small granules (0.25 – 1.0 mm) or filled with 0.5 g of large granules (1.0 – 2.0 mm).

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

## TECHNOLOGICAL CHARACTERISTICS

Geistlich Bio-Oss Pen® has the same technological characteristics (e.g., design, material) and intended use as its predicate device, Geistlich Bio-Oss® but is packaged in a syringe-like applicator for ease of delivery to the defect. The syringe-like applicator is similar to that of RTR Syringe.

## PERFORMANCE DATA

Bench testing was performed to confirm that the Geistlich Bio-Oss® granules in Geistlich Bio-Oss Pen® could be easily wet and that the Instructions for Use could be easily understood by clinical volunteers. Testing confirmed that Geistlich Bio-Oss Pen® was a convenient way to moisten Geistlich Bio-Oss® granules, as described in the Instructions for Use. In a handling test with clinical volunteers, the test results demonstrated that the Geistlich Bio-Oss Pen® could be easily used by clinicians. These two bench-type performance tests confirmed that the granules of Geistlich Bio-Oss Pen® could be easily mixed with normal saline or blood like those in the glass vials, and that the product could be used according to its Directions for Use by clinicians participating in the bench test.

Testing was performed to confirm that there was no change in the biocompatibility of the Geistlich Bio-Oss® granules due to the new packaging configuration (i.e., syringe-like

K120601

applicator) of Geistlich Bio-Oss Pen®. Biocompatibility testing was done per ISO 10993-18 (*Biological evaluation of medical devices – Part 18: Chemical characterization of materials*) and ISO 10993-5 (*Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity*). The results of biocompatibility testing confirmed that there were no leachables or extractables, or clinically relevant growth inhibition.

The results of these studies confirm the substantial equivalence of Geistlich Bio-Oss Pen® to its predicate device, Geistlich Bio-Oss®.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Geistlich Pharma AG
C/O Mr. Daniel A. Kracov
Counsel
Arnold & Porter LLP
555 Twelfth Street, NW
Washington, District of Columbia 20004

MAY 24 2012

Re: K120601
Trade/Device Name: Geistlich Bio-Oss Pen®
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: II
Product Code: NPM
Dated: May 1, 2012
Received: May 2, 2012

Dear Mr. Kracov:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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

Sincerely yours,

for

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

Enclosure

K120601

# Indications for Use

510(k) Number (if known): K120601

Device Name: Geistlich Bio-Oss Pen®

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- Augmentation or reconstructive treatment of the alveolar ridge;
- Filling of infrabony periodontal defects;
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- 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)

Susan Runyon

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



510(k) Number: K120601