



Geistlich Pharma AG  
% Roshana Ahmed  
Sr. Regulatory Specialist  
TELOS Partners LLC  
2850 Frontier Drive  
Warsaw, Indiana 46582

July 12, 2024

Re: K240661

Trade/Device Name: Geistlich Bio-Oss®  
Regulation Number: 21 CFR 872.3930  
Regulation Name: Bone Grafting Material  
Regulatory Class: Class II  
Product Code: NPM  
Dated: June 21, 2024  
Received: June 21, 2024

Dear Roshana Ahmed:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email ([DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

*Sherrill Lathrop Blitzer*

for Andrew Steen  
Assistant Director  
DHT1B: Division of Dental and  
ENT Devices  
OHT1: Office of Ophthalmic, Anesthesia,

Respiratory, ENT and Dental Devices  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

Submission Number (if known)

Device Name

Geistlich Bio-Oss®

Indications for Use (Describe)

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).

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

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## 510(k) Summary

### I. Submitter

Geistlich Pharma AG  
Bahnhofstrasse 40  
CH-6110 Wolhusen  
Switzerland  
Phone: +41 41 492 55 55

Contact Person: Marco Steiner, Deputy Director Regulatory Affairs  
Date Prepared: July 12, 2024

### II. Device

Device Proprietary Name:	Geistlich Bio-Oss®
Common or Usual Name:	Bone Grafting Material
Classification Name:	Bone grafting material, animal source
Regulation Number:	872.3930
Product Code:	NPM
Device Classification	II

### III. Predicate Device

Substantial equivalence is claimed to the following device:

- Geistlich Bio-Oss®, K122894, Geistlich Pharma AG

The following device is cited as a reference device:

- Orthoss®, K190754, Geistlich Pharma AG

### IV. Device Description

Geistlich Bio-Oss® is a biocompatible bone mineral matrix and is manufactured from purified spongiosa (cancellous) bovine bone mineral. The product is provided in granules or block form.

Geistlich Bio-Oss® serves as a matrix consisting of interconnected macro- and micropores. The material is highly porous, hydrophilic and has a large inner surface area. Geistlich Bio-Oss® is provided sterile via gamma irradiation or x-ray irradiation in the following configurations:

- Geistlich Bio-Oss® spongiosa (cancellous) granules (0.125 g, particle size 0.25 – 1.0 mm)
- Geistlich Bio-Oss® spongiosa (cancellous) granules (0.25 g, particle size 0.25 – 1.0 mm)
- Geistlich Bio-Oss® spongiosa (cancellous) granules (0.5 g, particle size 0.25 – 1.0 mm)
- Geistlich Bio-Oss® spongiosa (cancellous) granules (1.0 g, particle size 0.25 – 1.0 mm)
- Geistlich Bio-Oss® spongiosa (cancellous) granules (2.0 g, particle size 0.25 – 1.0 mm)
- Geistlich Bio-Oss® spongiosa (cancellous) granules (5.0 g, particle size 0.25 – 1.0 mm)
- Geistlich Bio-Oss® spongiosa (cancellous) granules (0.5 g, particle size 1.0 – 2.0 mm)
- Geistlich Bio-Oss® spongiosa (cancellous) granules (1.0 g, particle size 1.0 – 2.0 mm)
- Geistlich Bio-Oss® spongiosa (cancellous) granules (2.0 g, particle size 1.0 – 2.0 mm)
- Geistlich Bio-Oss® spongiosa (cancellous) block (approx. 1 x 1 x 2 cm)

## V. 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).

## VI. Comparison of Technological Characteristics

The Indications for Use Statement is identical to the predicate device.

The subject device is identical to the predicate device with respect to materials characteristics, manufacturing methods, packaging, and size. The subject device and the predicate device have identical final product specifications. A comparison table is provided below.

	<b>Subject Device</b>	<b>Geistlich Bio-Oss® (K122894)</b>	<b>Analysis</b>
<b>Material</b>	Mineral of bovine origin	Mineral of bovine origin	Same
<b>Shape</b>	Granules Block	Granules Block	Same
<b>Particle Sizes</b>	0.25 – 1.0 1.0 – 2.0	0.25 – 1.0 1.0 – 2.0	Same
<b>Configurations</b>	Granules: 0.125 g 0.25 g 0.5 g 1.0 g 2.0 g 5.0 g Block: 1 x 1 x 2 cm	Granules: 0.25 g 0.5 g 2.0 g 5.0 g Block: 1 x 1 x 2 cm	Different
<b>Single-Use</b>	Yes	Yes	Same
<b>Sterilization</b>	Gamma X-ray	Gamma	Different

The purpose of this submission is to obtain clearance for the use of x-ray irradiation as an alternative terminal sterilization method and the use of animal sourced materials from a new additional supplier in New Zealand and new abattoir in Australia. In addition, the product is being offered in two new volumes: 0.125 g (particle size 0.25 – 1.0 mm), 1.0 g (particle size 0.25 – 1.0 mm), and 1.0 g (particle size 1.0 – 2.0 mm). These changes do not raise different questions of safety and effectiveness and are addressed by the performance data cited below and provided within the submission.

Further to these changes, the product shelf life has been extended from 3 years to 4 years, storage temperatures for raw bones were updated, the product specification was clarified, the secondary packaging for the 20 mL vial was changed to a blister pack, and the gamma sterilization load was increased to improve production capacity. These changes were assessed, validated as appropriate, and documented under the quality system.

## **VII. Performance Data**

Mechanical testing (K122984), biocompatibility (K190754), sterilization (K122894), shelf-life (K190754), and non-clinical performance testing (K122894) from the applicant's own predicate and reference device were leveraged in support of substantial equivalence.

Based on the results of assessment, the following evaluations were undertaken:

- sterilization validation per ISO 11137-1, ISO 11137-2, and ISO 11137-3
- biocompatibility assessments per ISO 10993-1 and ISO 10993-5
- stability testing per ICH Q1A (R) stability testing guidelines
- characterization of structural and mechanical properties
- viral inactivation studies per ISO 22442-3 and ICH Q5A(R2) Draft Version

In addition, validation of raw materials from the new supplier was undertaken. The physical and chemical composition and appearance of the validation lots were characterized using the same tests and acceptance criteria as the final, finished product.

## **VIII. Conclusion**

The subject device is identical to the predicate device. The addition of x-ray irradiation as an alternative terminal sterilization method and introduction of an additional raw material supplier do not raise different questions of safety and effectiveness. Therefore, it is concluded that Geistlich Bio-Oss® is substantially equivalent to the identified predicate device.