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

July 11, 2025

Re: K251786
Trade/Device Name: Geistlich Bio-Oss®; Geistlich Bio-Oss Pen®
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: Class II
Product Code: NPM
Dated: June 11, 2025
Received: June 11, 2025

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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) 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K251786

Device Name

Geistlich Bio-Oss® and Geistlich Bio-Oss Pen®

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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 number."

510(k) Summary

I. Submitter

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

Contact Person: Erik Wirth, Team Lead Regulatory Services
Date Prepared: July 10, 2025

II. Device

Device Proprietary Name:	Geistlich Bio-Oss® Geistlich Bio-Oss Pen®
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®, K240661, Geistlich Pharma AG
- Geistlich Bio-Oss® Pen, K120601, Geistlich Pharma AG

The following device is referenced within the submission:

- Geistlich Bio-Flow®, K242510, Geistlich Pharma AG
- Geistlich Bio-Oss(R), K122894, Geistlich Pharma AG
- Bio-Oss Anorganic Bovine Bone, K970321, Geistlich-Pharma

IV. Device Description

Geistlich Bio-Oss® is a biocompatible bone mineral matrix and is manufactured from purified spongiosa (cancellous) bovine bone mineral granules. 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 and has a large inner surface area.
Geistlich Bio-Oss® is provided sterile 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)

Geistlich Bio-Oss Pen® is a pre-filled syringe-like applicator containing Geistlich Bio-Oss® granules. The pen allows for targeted delivery of Geistlich Bio-Oss® granules to the intended treatment site without the need for other sterile instruments.

Geistlich Bio-Oss Pen® is provided sterile in the following configurations:

- Geistlich Bio-Oss Pen® (filled with 0.25 g, particle size 0.25 – 1.0 mm)
- Geistlich Bio-Oss Pen® (filled with 0.5 g, particle size 0.25 – 1.0 mm)
- Geistlich Bio-Oss Pen® (filled with 0.5 g, particle size 1.0 – 2.0 mm)

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 and sterilization methods, packaging, and size. Both the subject and predicate devices have identical final product specifications.

	Subject Devices	**Geistlich Bio-Oss® (K240661)** **Geistlich Bio-Oss Pen® (K120601)**
Material	Geistlich Bio-Oss®	Same
Form	Block or Granules (Bio-Oss® Pen – granules prefilled in syringe like applicator)	Same
Particle Size	0.25 – 1.0 mm 1.0 – 2.0 mm	Same
Block Size	1 x 1 x 2 cm	Same
Single-Use	Yes	Same
Sterilization	Gamma X-ray (Geistlich Bio-Oss® only)	Same

The purpose of this submission is to obtain clearance for use of an alternate supplier of bovine raw material and to notify the Agency of non-significant changes to manufacturing facilities and equipment, and release testing methods. These changes do not raise different questions of safety and effectiveness when compared to the predicate device and the testing to support the minor technological differences are discussed in the Performance Data section below.

VII. Performance Data

Results from viral inactivation studies (K242510 and K240661), biocompatibility (K120601 and K240661), sterilization and shelf-life (K120601 and K240661), and bench and non-clinical/clinical performance (K120601, K240661, K122894 and K970321) studies from the applicant's own predicate and reference devices were leveraged in support of substantial equivalence.

The following standards were utilized:

- ISO 22442-1:2020
- ISO 22442-2:2020
- ISO 22442-3:2007
- ISO 10993-1:2018
- ISO 11137-1:2006
- ISO 11137-2:2013
- ISO 11137-3:2017
- ISO 11607-1/-2

Qualitative and quantitative handling and performance studies as well as a usability study were undertaken to support design modifications to the Geistlich Bio-Oss® Pen syringe.

VIII. Conclusion

The subject devices are identical to the predicate devices. The addition of a new raw material supplier does not raise different questions of safety and effectiveness. Therefore, it is concluded that Geistlich Bio-Oss® and Geistlich Bio-Oss Pen® are substantially equivalent to the identified predicate devices.