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

April 15, 2025

Re: K250833
Trade/Device Name: SwissMembrane X; SwissMembrane X Socket
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: Class II
Product Code: NPL
Dated: March 20, 2025
Received: March 19, 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K250833

Device Name
SwissMembrane X;
SwissMembrane X Socket

Indications for Use *(Describe)*

SwissMembrane X is intended for the following uses:
• augmentation around implants placed in immediate extraction sockets;
• augmentation around implants placed in delayed extraction sockets;
• localized ridge augmentation for later implantation;
• alveolar ridge reconstruction for prosthetic treatment;
• filling of bone defects after root resection, cystectomy, removal of retained teeth;
• guided bone regeneration in dehiscence defects; and
• guided tissue regeneration procedures in periodontal defects.

SwissMembrane X Socket is intended for the following uses:
• augmentation around implants placed in immediate extraction sockets;
• augmentation around implants placed in delayed extraction sockets;
• localized ridge augmentation for later implantation;
• alveolar ridge reconstruction for prosthetic treatment;
• filling of bone defects after root resection, cystectomy, removal of retained teeth;
• guided bone regeneration in dehiscence defects.

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.

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510(k) Summary

I. Submitter

Geistlich Pharma AG
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CH-6110 Wolhusen
Switzerland
Phone: +41 41 492 53 39

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

II. Device

Device Proprietary Name:	SwissMembrane X SwissMembrane X Socket
Common or Usual Name:	Resorbable Membrane for Guided Tissue and Bone Regeneration
Classification Name:	Bone Grafting Material
Regulation Number:	872.3930
Product Code:	NPL
Device Classification	II

III. Predicate Device

Substantial equivalence is claimed to the following devices:

Product Name	**510(k)**	**Applicant**
Geistlich Bio-Gide® and Geistlich Bio-Gide® Shape	K212463	Geistlich Pharma AG

IV. Device Description

SwissMembrane X and SwissMembrane X Socket are resorbable collagen membranes made of porcine collagen. The porous surface (facing the bone) allows the ingrowth of bone forming cells, and the dense surface (facing the soft tissue) prevents the ingrowth of fibrous connective tissue into the bone defect. The membranes are made of collagen without further cross-linking and are sterilized by gamma irradiation.

SwissMembrane X is provided in the following variants and sizes:

- SwissMembrane X D-Line
  - 13 x 25 mm (rectangle)
  - 25 x 15/25 mm (trapezoid)
  - 30 x 25/40 mm (trapezoid)
- SwissMembrane X Socket D-Line
  - 14 x 24 mm

V. Indications for Use

SwissMembrane X is intended for the following uses:

- augmentation around implants placed in immediate extraction sockets;
- augmentation around implants placed in delayed extraction sockets;
- localized ridge augmentation for later implantation;
- alveolar ridge reconstruction for prosthetic treatment;
- filling of bone defects after root resection, cystectomy, removal of retained teeth;
- guided bone regeneration in dehiscence defects; and
- guided tissue regeneration procedures in periodontal defects.

SwissMembrane X Socket is intended for the following uses:

- augmentation around implants placed in immediate extraction sockets;
- augmentation around implants placed in delayed extraction sockets;
- localized ridge augmentation for later implantation;
- alveolar ridge reconstruction for prosthetic treatment;
- filling of bone defects after root resection, cystectomy, removal of retained teeth;
- guided bone regeneration in dehiscence defects.

VI. Comparison of Technological Characteristics

The indications for use statements for the subject and predicate devices are identical.

The subject devices are equivalent to the predicate devices with respect to material characteristics, manufacturing and sterilization methods, packaging, and size. A comparison of the devices is provided in the table below.

	SwissMembrane X SwissMembrane X Socket	**Geistlich Bio-Gide® Geistlich Bio-Gide® Shape (K212463)**	**Analysis**
Manufacturer	Geistlich Pharma AG	Geistlich Pharma AG	Identical
Animal Material	Porcine collagen	Porcine collagen	Identical
Shape	Rectangle Trapezoid Pre-shaped	Rectangle Pre-shaped	Substantially equivalent
Sizes	SwissMembrane X D-Line: Rectangle:13x25 mm Trapezoid: 25x15/25 mm Trapezoid: 30x25/40 mm	Geistlich Bio-Gide® Rectangle: 13 x 25 mm Rectangle: 25 x 25 mm Rectangle: 30 x 40 mm Rectangle: 40 x 50 mm	Substantially equivalent
	SwissMembrane X Socket D-Line : Pre-shaped (14 x 24 mm)	Geistlich Bio-Gide® Shape: Pre-shaped (14 x 24 mm)	Identical
Single-Use	Yes	Yes	Identical
Sterilization	Gamma	Gamma	Identical

The purpose of this submission is to obtain clearance for the SwissMembrane X and SwissMembrane X Socket which are part of a new product line to the existing legally marketed Geistlich Bio-Gide® products. This new product line includes variants of different shapes and sizes which fall within the range of size configurations cleared under the predicate device. The differences between the subject and predicate device are addressed by information provided within this submission.

VII. Performance Data

Non-clinical data was not deemed necessary to support the extension to the product line. As the subject devices fall within the range of size configurations cleared under the predicate device, there is no new worst-case configuration.

Results from biocompatibility, sterilization, shelf-life, packaging validation, bench and clinical performance studies from the applicant's own predicate device (K212463) were leveraged in support of substantial equivalence.

VIII. Conclusion

The information provided above supports that SwissMembrane X and SwissMembrane X Socket are comparable to the predicate devices with respect to intended use and technological characteristics. Therefore, it is concluded that SwissMembrane X and SwissMembrane X Socket are substantially equivalent to the identified predicate devices.