January 22, 2026

Geistlich Pharma AG
% Veronica Downen
Director, Regulatory Affairs
Mcra, LLC
803 7th St. NW
Washington, District of Columbia 20001

Re: K251323
Trade/Device Name: Device 104 Particulate
Regulatory Class: Unclassified
Product Code: KGN
Dated: April 29, 2025
Received: April 29, 2025

Dear Veronica Downen:

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,

Yu-chieh Chiu -S

Yu-Chieh Chiu, Ph.D.
Assistant Director
DHT4B: Division of Plastic and
Reconstructive Surgery Devices
OHT4: Office of Surgical and
Infection Control 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)*
K251323

Device Name
Device 104 Particulate

Indications for Use *(Describe)*
Device 104 Particulate is intended to be used for the management of wounds including:
- partial and full thickness wounds
- pressure ulcers
- venous ulcers
- diabetic ulcers
- chronic vascular ulcers
- tunnel/undermined wounds
- surgical wounds (donor sites/grafts, post Mohs surgery, post laser surgery, podiatric, wound dehiscence)
- trauma wounds (abrasions, lacerations, second-degree burns and skin tears) and draining wounds.

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

Contact Person: Marco Steiner, Head RA Management
Date Prepared: January 22, 2026

II. Device

Device Proprietary Name:	Device 104 Particulate
Common or Usual Name:	Animal-derived, extracellular matrix wound care product
Product Code:	KGN
Device Classification	Unclassified

III. Predicate Device

Substantial equivalence is claimed to the following devices:

- MicroMatrix® (K172399)

The following reference device is cited within the submission:

- Geistlich Derma-Gide®, K182838, Geistlich Pharma AG

IV. Device Description

Device 104 Particulate is a wound care device derived from porcine peritoneum. The device is supplied in a particle form in units up to 500 mg and packed in sterile double layer packaging. The device consists of a collagen scaffold that protects the wound. Device 104 Particulate is terminally sterilized by gamma-irradiation.
The device can be applied directly to the wound bed. Alternatively, Device 104 Particulate can be hydrated with sterile saline to form a paste prior to application.

V. Indications for Use

Device 104 Particulate is intended to be used for the management of wounds including:

- partial and full thickness wounds
- pressure ulcers
- venous ulcers
- diabetic ulcers

- chronic vascular ulcers
- tunnel/undermined wounds
- surgical wounds (donor sites/grafts, post Mohs surgery, post laser surgery, podiatric, wound dehiscence)
- trauma wounds (abrasions, lacerations, second-degree burns and skin tears) and draining wounds.

VI. Comparison of Technological Characteristics

Device 104 is substantially equivalent to the predicate device with respect to intended use and technological characteristics. The intended use and indications for use are identical between the two devices. While there are minor differences in technological characteristics; however, these differences do not raise different questions of safety or effectiveness.

Both devices are made from porcine-derived collagen and appear as white to almost white particles. Collagen degradation rates and onset temperature are equivalent. Both devices are sterilized by irradiation and packaged in glass vials with rubber stoppers.

Device 104 Particulate has a lower pH (2.5–3.2) compared to the predicate (pH 7). However, this falls within the acceptable range established by precedent devices (e.g., K171645, K012990). Cytotoxicity testing confirmed the lower pH does not adversely impact cell viability and extracts of Device 104 Particulate were found to be non-irritating after intracutaneous injection in rabbits in accordance to ISO 10993-23: 2021.

In an excisional wound healing model in pigs, no significant differences in healing were observed between Device 104 Particulate and the predicate device. Macroscopic and histopathological analysis confirmed that Device 104 Particulate did not cause adverse tissue effects, showed time-related degradation without foreign body reactions, and was non-irritant.

VII. Safety and Performance Data

The following non-clinical tests were performed to support substantial equivalence:

- Characterization of chemical properties
    - Collagen Degradation
    - Onset Temperature by DSC
- Additional studies
    - Scanning Electron Microscopy
- Sterilization Validation per ISO 11137-1:2006, ISO 11137-2:2013, and ISO 11137-3:2017
- Packaging Validation per ISO 11607-1:2019, ASTM F1980:2007, ASTM F1886/F1886M:2016, ASTM F88:2015, ASTM F1929:2015, and ASTM F2096:2011
- Product stability testing per ICH Q1A(R)
- Biocompatibility Studies per ISO 10993-1:2018

VIII. Conclusion

The information provided above supports that Device 104 Particulate is as safe and effective as the predicate device. Although minor differences in design and technology exist between the subject and predicate device, performance testing demonstrates that these differences do not raise any new questions of safety and effectiveness. Therefore, it is concluded that Device 104 Particulate is substantially equivalent to the predicate device.