July 17, 2025

Geistlich Pharma AG
% Gretchen Upton
Regulatory Affairs Consultant
GxPartners LLC
7626 Prairie View Lane
Indianapolis, Indiana 46256

Re: K251556
Trade/Device Name: Device 300423 Granules
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable Calcium Salt Bone Void Filler Device
Regulatory Class: Class II
Product Code: MQV
Dated: May 14, 2025
Received: May 21, 2025

Dear Gretchen Upton:

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,

JESSE MUIR -S

Digitally signed by JESSE MUIR -S
Date: 2025.07.17 11:55:04 -04'00'

Jesse Muir, Ph.D.
Assistant Director
DHT6C: Division of Restorative,
Repair, and Trauma Devices
OHT6: Office of Orthopedic 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.

Submission Number *(if known)*

K251556

Device Name

Device 300423 Granules

Indications for Use *(Describe)*

Device 300423 Granules is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. Device 300423 Granules is indicated to be gently packed into bony voids or gaps of the skeletal system (i.e., posterolateral spine, ilium and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced with bone during the healing process.

Device 300423 Granules must be used with blood or autogenous bone marrow aspirate and autograft in posterolateral spine.

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 Regulatory Affairs Management

Date Prepared: May 14, 2025

II. Device

Device Proprietary Name:	Device 300423 Granules
Common or Usual Name:	Bone graft substitute
Classification Name:	Filler, Bone Void, Calcium Compound
Regulation Number:	CFR 888.3045 Bone grafting material
Product Code:	MQV
Device Classification	II

III. Predicate Device

Substantial equivalence is claimed to the following device:

- Device 300397 Putty (K241802)

IV. Device Description

Device 300423 Granules is an osteoconductive, dry, porous, resorbable bone graft substitute which consists of calcium phosphate granules of proprietary alpha-tricalcium phosphate (α-TCP) and hydroxyapatite (HAp). The single-patient, single-use product is supplied sterile (via X-ray irradiation) as 0.25-1 or 0.8-2 mm granules packaged in 6 mL glass vials. The glass vials containing Device 300423 Granules are individually packaged in A-PET blisters and sealed with polyethylene (HDPE) Tyvek film.

V. Indications for Use

Device 300423 Granules is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. Device 300423 Granules is indicated to be gently packed into bony voids or gaps of the skeletal system (i.e. posterolateral spine, ilium, and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced with bone during the healing process.

Device 300423 Granules must be used with blood or autogenous bone marrow aspirate and autograft in posterolateral spine.

VI. Comparison of Technological Characteristics

Device 300423 Granules is substantially equivalent to the predicate device in terms of intended use and technological characteristic.

Both devices are osteoconductive, resorbable bone void fillers intended to fill bony voids or gaps of the skeletal system that are caused by trauma or surgery and are not intrinsic to the stability of the bony structure. Device 300423 Granules is a dry, porous, resorbable biphasic calcium phosphate bone graft substitute in granular form comprised of a synthetic, porous, α-TCP (79% - 93%) and hydroxyapatite (7% - 21%) material. The predicate device, Device 300397 Putty, is made from the same calcium phosphate granules as Device 300423 Granules, which are mixed with Type I and III porcine collagen in a ratio of 80%/20%.

The primary differences between the subject device and the predicate are the final device composition prior to use and packaging.

Device 300423 Granules performed in a manner that was substantially equivalent to the predicate Device 300397 Putty in terms of manual palpation, radiographic and histological grade of bilateral spine fusion in the rabbit posterolateral spine fusion model.

Although a different packaging system is used for Device 300423 Granules and Device 300397 Putty, materials (glass vial and rubber stopper) used for Device 300423 Granules are unlikely to raise any specific biological concern.

Secondary differences include the granule size and appearance. The larger granules of Device 300423 Granules (0.8 - 2 mm) are within the range of the sizes approved within the predicate clearance K24182 (0.5 – 2 mm), whereas the granule size of the smaller granules significantly overlaps with the granule size of the predicate. The beige to off white granules vary slightly in color as compared to the predicate (white to off-white) due to lack of collagen during manufacture. This difference does not impact the safety or performance of the subject device.

As seen above, Device 300423 Granules is the same or similar to the predicate device in terms of intended use, sterilization and biological safety profile. The technological differences between the subject and predicate device do not raise new questions of safety and effectiveness and the data provided within this submission support that Device 300423 Granules is substantially equivalent to the identified predicate device.

VII. Safety & Performance Data

The following studies were performed to demonstrate substantial equivalence of 300423 Granules Spine to the predicate device:

Chemical Property Characterization Studies

- Product composition
- Phase Analysis by X Ray Diffraction
- Characterization by FT-IR
- SEM

Characterization of physical properties

- Pore Size and Pore Size Distribution
- Particle Size Distribution
- Tapped Density
- Verification of Device pH
- Liquid uptake
- Monitoring of Performance Parameters Over Time
  - Residual Porosity
  - Liquid uptake

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(R2)

Transport Simulation per ISTA 3A

Biocompatibility Studies per ISO 10993-1:2018

- Cytotoxicity per ISO 10993-5:2009
- Sensitization per ISO 10993-10:2010
- Irritation/Intracutaneous Reactivity per ISO 10993-10:2010
- Acute Systemic Toxicity per ISO 10993-11:2017
- Material Mediated Pyrogenicity per USP <151> / Ph. Eur. Section 2.6.8
- Subacute Systemic Toxicity per ISO 10993-6:2016 and ISO 10993-11:2017
- Subchronic Systemic Toxicity per ISO 10993-6:2016 and ISO 10993-11:2017
- Genotoxicity per ISO 10993-3:2014
- Implantation (local tissue reaction) per ISO 10993-6:2016
- Hemocompatibility per ASTM F756:2017 and ISO 10993-4:2017
- Chronic Systemic Toxicity per ISO 10993-11:2017
- Elemental Impurities Analysis ICH Q3D (R2):2022 and ISO 10993-17:2023

In addition, the safety and performance of Device 300423 Granules was evaluated as a bone graft extender in the NZ White Rabbit Single Level Spinal Fusion Model. The performance of the device was evaluated in accordance with the requirements of the FDA guidance on calcium salt bone void filler guidance while the local tissue reaction was evaluated in accordance with the requirements of ISO 10993-6:2016.

VIII. Conclusion

The information provided above supports that Device 300423 Granules 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 300423 Granules is substantially equivalent to the predicate device.