June 2, 2026

Geistlich Pharma AG
% Roshana Ahmed
Principal Consultant
QUARAS, LLC
Contact Address

Re: K260364
Trade/Device Name: Device 300419 Strip
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable Calcium Salt Bone Void Filler Device
Regulatory Class: Class II
Product Code: MQV
Dated: May 1, 2026
Received: May 1, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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: 2026.06.02 09:58:00 -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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K260364

Please provide the device trade name(s).

Device 300419 Strip

Please provide your Indications for Use below.

Device 300419 Strip is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. Device 300419 Strip 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 300419 Strip must be used with blood or autologous bone marrow aspirate and autograft in posterolateral spine.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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: January 30, 2026

II. Device

Device Proprietary Name:	Device 300419 Strip
Common or Usual Name:	Bone Void Filler
Classification Name:	Filler, Bone Void, Calcium Compound
Regulation Number:	888.3045
Product Code:	MQV
Device Classification	II

III. Predicate Device

Substantial equivalence is claimed to the following devices:

- MASTERGRAFT® Putty, K071813, Medtronic Sofamer Danek

The following device is referenced within the submission:

- Device 300397 Putty, K241802, Geistlich Pharma AG

IV. Device Description

Device 300419 Strip is an osteoconductive, porous bone void filler consisting of proprietary synthetic porous biphasic calcium phosphate granules (90% alpha-tricalcium phosphate (α-TCP) and 10% hydroxyapatite (HA)) in a carrier of bovine collagen. The single-use product is supplied in three (3) sizes (3 cc, 6 cc, and 12 cc) as a sterile dry and porous matrix. Before application, the device is hydrated with autogenous bone marrow aspirate, blood, or sterile non-pyrogenic saline.

V. Indications for Use

Device 300419 Strip is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. Device 300419 Strip 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 300419 Strip must be used with blood or autologous bone marrow aspirate and autograft in posterolateral spine.

VI. Comparison of Technological Characteristics

There are slight differences between the subject and predicate device with respect to the indications for use statement; however, these differences do not alter the overall intended use of the subject device. The indications for use statement for the subject device is identical to that of Device 300397 Putty (K241802). These devices are 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 300419 Strip and the predicate device are sterile, single use, osteoconductive bone void fillers.

The subject device consists of calcium phosphate granules (90%) and bovine collagen (10%). The calcium phosphate granules (0.5 - 2 mm) are comprised of synthetic, porous, biphasic, α-TCP and hydroxyapatite. In comparison, the predicate device is composed of ceramic (80%) and bovine collagen (20%). The predicate devices' calcium phosphate granules contain β-TCP (85%) and hydroxyapatite (15%). The use of a different TCP polymorph in the subject device does not raise different questions of safety and effectiveness as the polymorphs contain the same structural elements (i.e., Calcium and Phosphate ions), and identical stoichiometry (i.e., the ratio of calcium to phosphorus is 1.5). Furthermore, the reference device (K241802) is comprised of the same calcium phosphate granules as the subject device. The difference in granule to collagen ratio does not raise different questions of safety and effectiveness. Product safety and efficacy are demonstrated through biocompatibility and animal implantation studies.

The granule size for Device 300419 Strip is slightly larger than that of the predicate device; however, as demonstrated through animal testing, there are no new or different concerns raised by the larger size.

The use of x-ray sterilization is addressed via sterilization validation; this difference does not raise any new questions. According to FDA guidance *Information in Premarket Notification 510(k) Submissions for Devices Labeled as Sterile* x-ray as well as electron irradiation are well established Category A sterilization methods.

Further, biocompatibility testing of the product demonstrated that the Device 300419 Strip is biocompatible. In addition, *in vivo* testing in the rabbit posterolateral spine fusion model demonstrated that the Device 300419 Strip performed in a manner that was substantially equivalent to the predicates in terms of both graft absorption and bone formation.

Device 300419 Strip is similar to the predicate device in terms of intended use 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 300419 Strip is substantially equivalent to the predicate device.

VII. Performance Data

The following non-clinical data was provided within this submission to demonstrate substantial equivalence:

- Characterization of chemical properties
    - Composition
    - Residue on Ignition
    - Phase Analysis by X Ray Diffraction
    - Characterization by FT-IR
    - Amino Acid Composition
    - Scanning Electron Microscopy
    - Molecular Weight Distribution of Collagen
    - Onset Temperature by Differential Scanning Calorimetry
    - Enzymatic Collagen Degradation
- Characterization of physical properties
    - Pore Size and Pore Size Distribution
    - Particle Size Distribution
    - Weight, Dimension, and Density
- Material Handling Study

The safety and performance of Device 300419 Strip 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.

Device 300419 Strip was hydrated with bone marrow aspirate (BMA) or with blood and mixed 1:1 with autograft; the predicate device was hydrated with BMA and mixed 1:1 with autograft. The graft material was placed adjacent to the vertebral body as well as between decorticated transverse processes. Progression in healing versus time was observed when implanted on decorticated transverse processes in the posterolateral space. Further healing was observed at the host decorticated transverse process interfaces with new bone formation with active osteoblasts present directly on the surface of the graft material and autograft material. New bone formation directly on the surfaces of graft material and autograft was also observed. The progression and maturation of the fusions treated with Device 300419 Strip hydrated with BMA or blood were confirmed via histology. Bone remodeling and formation of new marrow spaces was seen at the decorticated host transverse process interface as new bone formation on and through the graft material which was associated with a reduction in local inflammatory cells.

The purity profile of the final finished Device 300419 Strip was evaluated through elemental impurities analysis ICP-MS and a toxicological assessment was performed according to ISO 10993-17:2023 / ICH Q3D (R2):2022. Additionally, device 300419 Strip was tested for cytotoxicity in accordance with the provisions of ISO 10993-5:2009.

Sterilization Validation was conducted per ISO 11137-1:2006, ISO 11137-2:2013, and ISO 11137-3:2017

The following testing was referenced to the applicant's own device (K241802) in support of the subject device safety:

- Biocompatibility Studies per ISO 10993-1:2018
    - 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
    - Hemocompatibility per ASTM F756:2017 and ISO 10993-4:2017
    - Chronic Systemic Toxicity per ISO 10993-11:2017
- Packaging Validation per ISO 11607-1:2019, ASTM F1980:2007, ASTM F1886/F1886M:2016, ASTM F88:2015, ASTM F1929:2015, and ASTM F2096:2011

VIII. Conclusion

The information provided above supports that Device 300419 Strip 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 300419 Strip is substantially equivalent to the predicate device