November 8th, 2024

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

Re: K241802
Trade/Device Name: Device 300397 Putty
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable Calcium Salt Bone Void Filler Device
Regulatory Class: Class II
Product Code: MQV
Dated: October 4, 2024
Received: October 4, 2024

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,

Robert M. Stefani -S
2024.11.08 12:42:36 -05'00'

For: 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)*

K241802

Device Name

Device 300397 Putty

Indications for Use *(Describe)*

Device 300397 Putty is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. Device 300397 Putty 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 300397 Putty 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.

510(k) Summary

I. Submitter

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

Contact Person: Marco Steiner, Deputy Director Regulatory Affairs
Date Prepared: November 1, 2024

II. Device

Device Proprietary Name:	Device 300397 Putty
Common or Usual Name:	Bone Void Filler
Classification Name:	Filler, Bone Void, Calcium Compound
Regulation Number:	CFR 888.3045
Product Code:	MQV
Device Classification	II

III. Predicate Device

Substantial equivalence is claimed to the following device:

- MASTERGRAFT® Putty, K071813, Medtronic Sofamor Danek

The following reference devices are cited within the submission:

- Actifuse ABX E-Z-fil Bone Graft Substitute, K081979, ApaTech Limited
- OsteoFlo® NanoPutty® - Quadphasic Synthetic Bone Graft, K200064, SurGen Tec LLC
- Geistlich Bio-Gide, K192042, Geistlich Pharma AG

IV. Device Description

Device 300397 Putty is an osteoconductive, porous, resorbable bone graft substitute which consists of calcium phosphate granules (α-TCP and hydroxyapatite) and Type I and III porcine collagen. The single-patient, single-use product is supplied in three (3) sizes as a sterile, dry block. When mixed with autogenous bone marrow aspirate, blood or sterile non-pyrogenic saline, the product forms a moldable non-setting putty (net volume: 2.5 cc, 5 cc or 10 cc).

V. Indications for Use

Device 300397 Putty is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. Device 300397 Putty 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 300397 Putty must be used with blood or autogenous bone marrow aspirate and autograft in posterolateral spine.

VI. Comparison of Technological Characteristics

Device 300397 Putty is substantially equivalent to the predicate device in terms of intended use and 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. Both 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 300397 Putty and the predicate device are osteoconductive materials which utilize the same ratio of inorganic to organic material, are sterilized via irradiation, and are biologically safe. The subject device consists of calcium phosphate granules and porcine collagen. The calcium phosphate granules (0.5 – 2 mm) are comprised of a synthetic, porous, biphasic α-TCP/hydroxyapatite material. The use of a different TCP polymorph in the subject device does not raise different questions of safety and effectiveness as the polymorphs share the same structural composition (i.e., the crystal structures are similar and have almost identical unit cell size and volume) and chemical stoichiometry.

The porcine collagen utilized in Device 300397 Putty is used in Geistlich Pharma AG's dental products and the identified raw material sources were previously cleared by the FDA.

The granule size for Device 300397 Putty is slightly larger than that of the predicate device; however, as demonstrated through performance testing, there are no new or different concerns raised by the larger size.

As seen above, Device 300397 Putty 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 300397 Putty is substantially equivalent to the identified predicate device.

VII. Safety & Performance Data

The following studies were successfully executed.

- Characterization of chemical properties
  - Amino Acid Composition
  - Product composition (Residue on ignition)
  - Phase Analysis by X Ray Diffraction
  - Characterization by FT-IR
  - SEM
  - Molecular Weight Distribution of Soluble Protein
  - Onset Temperature and Enthalpy of Protein Denaturation by Differential Scanning Calorimetry
  - Enzymatic Collagen Degradation
- Characterization of physical properties
  - Pore Size and Pore Size Distribution
  - Particle Size Distribution
  - Weight, Dimension, and Density
  - Determination of Hydrated Volume
- Material Handling Studies
- 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

In addition, the safety and performance of Device 300397 Putty 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 300397 Putty 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 300397 Putty 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.

VIII. Conclusion

The information provided above supports that Device 300397 Putty 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 300397 Putty is substantially equivalent to the predicate device.