June 23, 2019

Geistlich Pharma AG
% Roshana Ahmed, M.A., RAC
Associate Director, Regulatory Affairs
TELOS Partners, LLC
571 Christina Lake Drive
Lakeland, Florida 33813

Re: K190754
Trade/Device Name: Orthoss®
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: March 22, 2019
Received: March 25, 2019

Dear Ms. 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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Laurence D. Coyne, Ph.D.
Assistant Director
DHT6C: Division of Stereotaxic, Trauma and Restorative 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K190754

Device Name
Orthoss(R)

Indications for Use *(Describe)*

ORTHOSS® is an implant intended to fill bony voids or gaps of the skeletal system (i.e. extremities, posterolateral spine and pelvis). ORTHOSS® can be used with autograft as a bone graft extender in a posterolateral spine fusion. These osseous defects may be surgically created or be the result of traumatic injury to the bone and are not intrinsic to the stability of the bony structure. The device resorbs and is replaced with bone during the healing process.

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.

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510(k) Summary

I. Submitter

Geistlich Pharma AG
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Switzerland
Phone: +41 41 492 67 64

Contact Person: Marco Steiner, Deputy Director Regulatory Affairs
Date Prepared: May 20, 2019

II. Device

Device Proprietary Name:	Orthoss®
Common or Usual Name:	Resorbable Bone Void Filler
Classification Name:	Resorbable calcium salt bone void filler
Regulation Number:	21 CFR 888.3045
Product Code:	MQV
Device Classification	II

III. Predicate Device

Substantial equivalence is claimed to the following device:

- ORTHOSS® Resorbable Bone Void Filler, K090401, Geistlich Pharma AG

The following reference devices are cited within the submission:

- Geistlich Bio-Oss, K122894, Geistlich Pharma AG
- MASTERGRAFT® Resorbable Ceramic Granules, K082918, Medtronic Sofamer Danek
- Geistlich Bio-Oss Pen, K120601, Geistlich Pharma AG

IV. Device Description

Orthoss® is an inorganic bone matrix, manufactured from bovine bone, with an interconnected macro- and microporous structure that supports the formation and ingrowth of new bone. Over time, Orthoss® is partially remodeled by osteoclasts and osteoblasts (physiological remodeling).

The single-use product is provided sterile (via gamma irradiation) in block (1 x 1 x 2 cm and 2 x 2 x 1.3 cm) or granular (1 - 2 mm and 2 - 4 mm) form in double-blister packs or glass vials in a blister pack, respectively.

V. Indications for Use

Orthoss® is an implant intended to fill bony voids or gaps of the skeletal system (i.e. extremities, posterolateral spine and pelvis). Orthoss® can be used with autograft as a bone graft extender in a posterolateral spine fusion. These osseous defects may be surgically created or be the result of traumatic injury to the bone and are not intrinsic to the stability of the bony structure. The device resorbs and is replaced with bone during the healing process.

VI. Comparison of Technological Characteristics

The subject device is similar to the predicate device with respect to materials characteristics, manufacturing and sterilization methods, packaging, and size. Both the subject and predicate device have identical final product specifications.

Since prior clearance of the device, the following minor changes were made:

- change from an aluminum vial cap to a polyethylene vial cap;
- slight changes in manufacturing and processes;
- addition of alternative raw material supplier;
- addition of a new filling volume of 1 - 2 mm, 1 g (~2.5 cc); and
- packaging change for Orthoss granules from glass vial in a peel pouch to glass vial in blister pack

These changes do not raise different questions of safety and effectiveness and are addressed by the performance testing identified below.

VII. Performance Data

The following performance data were provided in support of the substantial equivalence determination:

- sterilization validation per ISO 11137-1:2006, ISO 11137-2:2013, and ISO 11137-3:2017;
- pyrogenicity per USP <151> and endotoxin per USP <85>;
- shelf-life studies per ICH Q1A (R2);
- packaging validation per ISO 11607-1:2009/ Amd 2014 and ISO 11607-2:2006/ Amd 2014;
- biocompatibility per ISO 10993-1:2018;
- X-ray, Fourier Transform Infrared, and HG-Pressure Porosimetry analysis; and
- validation of extended indication in a suitable study model.

Summary of Animal Study

The performance of Orthoss® and MASTERGRAFT® Resorbable Ceramic Granules (K082918) as autograft extenders were evaluated in a validated Boden rabbit spinal fusion model by determining the effect of the test article relative to iliac crest bone graft control (autograft) and MASTERGRAFT® Resorbable Ceramic Granules.

Rabbits were randomized to receive Orthoss®, MASTERGRAFT® Resorbable Ceramic Granules, or autograft control. Prior to surgery, lateral radiographs were taken for evidence of tibial growth plate closure and blood was drawn for routine biochemistry and hematology tests.

Evaluation of the local biological effects after implantation was conducted at 6, 9, and 12 weeks after implantation and examined at the transverse process and in the middle of the fusion mass. There were no adverse events or device related failures noted during harvesting.

Results of the study demonstrate that the subject and predicate device performed in a similar manner with respect to radiographic appearance, micro-computed tomography, and histology, and support a determination of substantial equivalence. Evidence of new bone formation as well as resorption and remodeling of the graft materials were observed via radiographs and micro-computed tomography. No differences with respect to the distribution of findings for manual palpation between the subject device and predicate device test groups were observed and the multidirectional flexibility of the lumbar spine in animals treated with the subject device and predicate device were similar.

Histological analysis showed normal patterns of bone healing in the test group and similar to the predicate group as well as the positive control. New bone formation and bone remodeling occurred with time reflecting a normal in vivo bone formation pathway for the test material as well as the predicate. There was presence of some inflammatory cells as the subject and predicate devices degraded over time.

The performance of positive control group (autograft) was consistent with the published data on the model as well as with the experience of the study site.

VIII. Conclusion

The information provided above supports that Orthoss® is as safe and effective as the predicate device. Non-clinical studies support the expansion to the indications for use statement and the safe and effective performance of the product. Therefore, it is concluded that Orthoss® is substantially equivalent to the predicate device.