

III 18 2014

## 2. 510(k) Summary

### GEISTLICH MUCOGRAFT® and GEISTLICH MUCOGRAFT® SEAL

#### SPONSOR

Geistlich Pharma AG  
Bahnhofstrasse 40  
CH-6110 Wolhusen  
Switzerland

Contact Person: Daniel Kracov, Arnold & Porter, LLP  
E-mail: Daniel.Kracov@aporter.com  
Phone: 202-942-5120  
Fax: 202-942-5999  
Date Prepared: 03 February 2014

#### DEVICE NAME

Proprietary Name: Geistlich Mucograft® and Geistlich Mucograft® Seal  
Common/Usual Names: Collagen Matrix  
Classification Name: Barrier, Animal Source, Intraoral (NPL)  
21 CFR Part 872.3930

#### PREDICATE DEVICES

Mucograft® (K102531, K073711, K061244, K012423)

#### DEVICE DESCRIPTION

Geistlich Mucograft® and Geistlich Mucograft® Seal are surgically implanted, fully resorbable devices intended for oral tissue regeneration.

Geistlich Mucograft® and Geistlich Mucograft® Seal are collagen matrices obtained by a standardized controlled manufacturing process. The matrices are made of collagen without further cross-linking. The collagen is extracted from veterinary certified pigs and is carefully purified to avoid antigenic reactions. All configurations of the product are sterilized in a double package by gamma irradiation. Geistlich Mucograft® and Geistlich Mucograft® Seal are composed of two structures: one smooth structure and one porous structure. The device allows tissue adherence as a prerequisite for favorable wound healing. The "outer" side (*i.e.*, turned towards the soft tissue) with a smooth surface consists of compact collagen and has a smooth texture with the appropriate elastic properties to accommodate suturing. The "inner" porous structure consists of collagen fibers in a loose, porous arrangement to allow cell invasion for soft tissue ingrowth. This roughened surface is placed next to the host tissue to facilitate tissue integration.

Available Products:

- Geistlich Mucograft® 15x20 mm
- Geistlich Mucograft® 20x30 mm
- Geistlich Mucograft® Seal 8 mm diameter

**INTENDED USE**

Geistlich Mucograft® and Geistlich Mucograft® Seal are indicated for:

- Covering of implants placed in immediate or delayed extraction sockets;
- Localized gingival augmentation to increase keratinized tissue (KT) around teeth and implants;
- Alveolar ridge reconstruction for prosthetic treatment;
- Recession defects for root coverage.

**SUMMARY OF TECHNOLOGICAL CHARACTERISTICS**

Geistlich Mucograft® is the same as the predicate device, Mucograft®. Geistlich Mucograft® Seal is a new size and shape, and has the same chemical composition and same materials as the predicate device, Mucograft®. Although the size and shape of Geistlich Mucograft® Seal has been modified, the differences do not change the intended use of the device.

Thus, with the exception of its size and shape, Geistlich Mucograft® Seal is identical to Geistlich Mucograft® and the predicate device, Mucograft®.

**SUMMARY OF DATA TO SUPPORT SUBSTANTIAL EQUIVALENCE**

Bench-type evaluations confirmed that Geistlich Mucograft® Seal is easily sutured in two extraction socket models. Evaluations by Geistlich and by clinicians confirmed that the configuration can be sutured readily to an extraction socket. These evaluations also demonstrated that Geistlich Mucograft® Seal should be sutured in place in a dry state (rather than semi-wet or wet) in treating extraction sockets.

This submission relies upon data previously submitted in support of Mucograft® including:

- Sterilization validation
- Packaging materials
- Biocompatibility testing
- Performance testing (Animal and Clinical)

**CONCLUSION**

It is strongly believed that there are no new or different questions regarding safety and effectiveness if Geistlich Mucograft® and Geistlich Mucograft® Seal are used according to their intended use.

Based on the data provided within this 510(k) submission as summarized above, it can be concluded that Geistlich Mucograft® and Geistlich Mucograft® Seal are substantially equivalent to the predicate device Mucograft®.



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - WO66-G609  
Silver Spring, MD 20993-0002

July 18, 2014

Geistlich Pharma Ag  
C/O Mr. Daniel Kracov  
Arnold & Porter LLP  
555 Twelfth Street, NW  
Washington, DC 20004

Re: K140518  
Trade/Device Name: Geistlich Mucograft® and Geistlich Mucograft® Seal  
Regulation Number: 21 CFR 872.3930  
Regulation Name: Bone Grafting Material  
Regulatory Class: Class II  
Product Code: NPL  
Dated: June 17, 2014  
Received: June 18, 2014

Dear Mr. Kracov:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

*Tejasri Purohit-Sheth, M.D.*  
Tejasri Purohit-Sheth, M.D.  
Clinical Deputy Director  
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.  
Director  
Division of Anesthesiology, General Hospital,  
Respiratory, Infection Control and  
Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**Indications for Use**

510(k) Number (if known)

K140518

Device Name

Geistlich Mucograft(R) and Geistlich Mucograft(R) Seal

Indications for Use (Describe)

Geistlich Mucograft® and Geistlich Mucograft® Seal are indicated for:

- Covering of implants placed in immediate or delayed extraction sockets
- Localized gingival augmentation to increase keratinized tissue (KT) around teeth and implants
- Alveolar ridge reconstruction for prosthetic treatment
- Recession defects for root coverage

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)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

**Sheena A. Green -S**

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