K102531

NOV 17 2010

510(k) Summary

MUCOGRAFT®

1. SPONSOR

Ed. Geistlich Soehne Ag für Chemische Industrie
Geistlich Pharma Ag
Bahnhofstrasse 40
CH-6110 Wolhusen
SWITZERLAND

Contact Person: Peter S. Reichertz, (202) 772-5333
Date Prepared: October 29, 2010

2. DEVICE NAME

Proprietary Name	MUCOGRAFT®
Common/Usual Name:	Collagen Matrix
Classification Name:	Barrier, Animal Source, Dental

3. PREDICATE DEVICES

MUCOGRAFT® (K012423, K061244 and K073711)
DYNAMATRIX K010952

4. INTENDED USE

MUCOGRAFT® Collagen Matrix currently is indicated for:

- Simultaneous use of GBR-membrane (MUCOGRAFT) and implants;
- Covering of implants placed in immediate extraction sockets;
- Covering of implants placed in delayed extraction sockets;
- Localized ridge augmentation for later implantation;
- Alveolar ridge reconstruction for prosthetic treatment;
- Covering of bone defects after root resection, cystectomy, removal of retained teeth;
- Guided bone regeneration in dehiscence defects; and
- Guided tissue regeneration procedures in periodontal and recession defects.

K102531

5. DEVICE DESCRIPTION

MUCOGRAFT® is a pure collagen membrane obtained by a standardized controlled manufacturing process. The membrane is made of collagen type I and type III without further cross-linking or chemical treatment. The collagen is extracted from veterinary certified pigs and is carefully purified to avoid antigenic reactions. MUCOGRAFT® is sterilized in double blisters by gamma irradiation. MUCOGRAFT® has a bilayer structure with one smooth, non-permeable layer and one porous. The "outer," smooth side has a smooth surface which is cell occlusive and prevents cell adhesion and acts as a barrier. It allows tissue adherence favoring wound healing. This side is turned towards the soft tissue. The smooth texture has appropriate elastic properties to accommodate suturing to the host mucosal margins and to protect the graft material from oral trauma during biodegradation and healing. The "inner" porous layer consists of collagen fibers in a loose, porous arrangement to enable cell invasion. This porous layer is made from pig skin. This side is turned toward the bone defect and/or soft tissue to encourage bone-forming cells and tissue growth and to stabilize the blood clot.

6. BASIS FOR SUBSTANTIAL EQUIVALENCE

MUCOGRAFT® collagen matrix is substantially equivalent to Geistlich's existing products MUCOGRAFT® (K012423, K061244 and K073711) and DYNAMATRIX® (K082058 and K010952). The current 510(k) requests clearance of MUCOGRAFT® for a revised set of indications regarding guided tissue regeneration, as follows:

- 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

These indications are similar to those accepted for MUCOGRAFT® and also for DYNAMATRIX®, which is cleared for gingival augmentation. MUCOGRAFT®, like DYNAMATRIX®, is a collagen membrane used in dental grafting procedures.

Preclinical and clinical studies support the safety and efficacy of the product for these indications for use.

K102531

Two preclinical studies have been conducted in two animal models: these studies provide evidence that Mucograft can be used successfully for dermal grafting (Wehrhan et al. 2010) and oral soft tissue augmentation (Herford and Boyne 2002). Wehrhan et al. chose a porcine model for their study, and Herford and Boyne used a primate model.

The two preclinical studies provide evidence of the following outcomes with Mucograft:

- Uneventful healing (Herford and Boyne 2002, Wehrhan et al. 2010); and
- Normal-appearing tissue: (1) Normal-appearing mucosa, complete re-epithelialization and generation of attached mucosa/ keratinized tissue (Herford and Boyne 2002); and (2) Similar revascularization and epithelialization to split thickness autogenous graft (Wehrhan et al. 2010).

Clinical studies have been conducted to evaluate the use of (1) Mucograft, as well as its predicate DynaMatrix, for gingival augmentation to increase keratinized tissue (KT, also referred to as "keratinized gingival" or "KG") and/or tissue thickness and (2) Mucograft for root coverage. These clinical studies provide evidence for the safe and effective use of Mucograft when placed (1) on top of a surgically-prepared wound bed or underneath a surgical flap, and (2) around teeth or dental implants.

The clinical studies (and their respective manuscripts, publications, or other source documents) provide clinical evidence of the device's use for gingival augmentation and root coverage procedures and demonstrates that it can be used safely and effectively on top of a surgically-created wound bed, underneath a surgical flap, around teeth, and around dental implants. In addition, the results with MUCOGRAFT® are similar to the published results reported for DynaMatrix.

This body of valid scientific evidence substantiates the proposed, more specific wording changes to the indications for use statement (changes are in **bold**):

- Localized **gingival augmentation to increase keratinized tissue (KT) around teeth or implants;**
- Localized **gingival augmentation to increase tissue thickness around teeth or implants;** and
- Recession defects **for root coverage.**

K102531

Charles A. A practice-based clinical research evaluation of the effectiveness of a collagen matrix used to augment keratinized tissue around dental implants. Manuscript in preparation.

Herford AS, Akin A, Cicciu M, Maiorana C, Boyne PJ. Use of a porcine collagen matrix as an alternative to autogenous tissue for grafting oral soft tissue defects. J Oral Maxillofac Surg 68:1463-1470, 2010.

Herford AS and Boyne PJ. Evaluation of a special collagen implant material as a substitute for free mucosal or skin grafts in oral soft tissue surgery. Proceedings of the American Institute of Oral Biology, Palm Springs, CA, October 2002 (pp 103-109).

McGuire MK and Scheyer ET. Xenogeneic collagen matrix with coronally advanced flap compared to connective tissue with coronally advanced flap for the treatment of dehiscence-type recession defects. J. Periodontol 81:1108-1117, 2010.

Nevins M, Nevins ML, Camelo M, Borges Camelo JM, Schupbach P, Kim DM. The clinical efficacy of DynaMatrix Extracellular Membrane in augmenting keratinized tissue. Int J Periodontics Restorative Dent. 30:151-161, 2010.

Panaite D. Practice-based clinical research evaluation of the effectiveness of Mucograft® Collagen Matrix to increase keratinized tissues around dental implants. Abstract presented at the 24th annual meeting of the Academy of Osseointegration (San Diego, CA, February 26-28, 2009).

Sanz M, Lorenzo R, Aranda JJ, Martin C, Orsini M. Clinical evaluation of a new collagen matrix (Mucograft® prototype) to enhance the width of keratinized tissue in patients with fixed prosthetic restorations: A randomized prospective clinical trial. J Clin Periodontol. 36:868-876, 2009. Epub 2009 Aug 12

Wehrhan F, Nkenke E, Melnychenko I, Amann K, Schlegel KA, Goerlach C, Zimmermann W-H, Schultze-Mosgau S. Skin repair using a porcine collagen I/III membrane – Vascularization and epithelialization properties. Dermatol Surg 36:919-930, 2010.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

NOV 17 2010

Ed. Geistlich Soehne Ag Fur Chemische Industrie
C/O Mr. Peter S. Reichertz
Sheppard Mullin Richter & Hampton LLP
1300 I Street N.W., 11th Floor East
Washington, DC 20005

Re: K102531
Trade/Device Name: MUCOGRAFT® Collagen Matrix
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: II
Product Code: NPL
Dated: October 29, 2010
Received: November 1, 2010

Dear Mr. Reichertz:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K102531

Indications for Use

510(k) Number (if known):

Device Name: MUCOGRAFT® Collagen Matrix.

Indications for Use:

- 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;
- guided tissue regeneration procedures in recession defects for root coverage

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _X_ (Part 21 CFR 801 Subpart D)

OR

Over-the-Counter Use _____ (21 CFR 801 Subpart C)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K102531