K073711

510(k) Summary

MUCOGRAFT®

MAY 30 2008

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: May 22, 2008

2. DEVICE NAME

Proprietary Name	MUCOGRAFT® Collagen Matrix
Common/Usual Name:	Resorbable Bilayer Membrane for Guided Tissue and Bone Regeneration
Classification Name:	Barrier, Animal Source, Dental

3. PREDICATE DEVICES

MUCOGRAFT® (K012423 and K061244)
BIO-GIDE® (K960724; K042197; and K050446)

4. INTENDED USE

MUCOGRAFT® Collagen Matrix is recommended 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.

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. It is made from the peritoneum of pigs. 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® resorbable bilayer membrane (K012423 and K061244) and BIO-GIDE® resorbable bilayer membrane for guided tissue and bone regeneration (subject to K960724; K042197; and K050446). The differences between the new product and the BIO-GIDE and MUCOGRAFT® products cleared previously via K061244 and K042197, respectively, are the following: (1) changes to the manufacturing process, including a change in the concentration and duration of the alkaline treatment step, a new freeze-dryer, and the solvent cleaning phase being performed earlier in the process; (2) a change in the blister material from polystyrene (PS) to amorphic polyethylene terephtalate (A-PET); (3) changes to the product specifications, including a parametric release for the Gamma-Sterilization, and the omission of certain release controls; (4) expanded indication for use in Guided Tissue Regeneration; (5) a new-layout for the product label and packaging; and (6) the thickness of membrane when dry is 2.5 mm to 5 mm as opposed to 2 mm with MUCOGRAFT® Resorbable Bilayer Membrane, but when wet and placed into a defect, both are approximate 1 mm. The proposed additional indication is for "guided tissue regeneration procedures in periodontal defects." Included by reference are all data submitted in the previous notification and clearance of BIO-GIDE® (K042197) and MUCOGRAFT® Resorbable Bilayer Membrane (K061244).

MUCOGRAFT®, like BIO-GIDE®, is a collagen membrane used in dental grafting procedures. MUCOGRAFT® was previously determined to be substantially equivalent to BIO-GIDE® and is cleared for all of the indications for which BIO-GIDE® is cleared.

The following is a table comparing MUCOGRAFT® Collagen Matrix to MUCOGRAFT® Resorbable Bilayer Membrane for guided tissue and bone regeneration.

Table 1: MUCOGRAFT® Resorbable Bilayer Membrane (Predicate Device) vs. MUCOGRAFT® Collagen Matrix
Comparison Chart

	MUCOGRAFT® Resorbable Bilayer Membrane	MUCOGRAFT® Collagen Matrix
Intended Use	Used for guided tissue regeneration procedures in periodontal defects to enhance regeneration of the periodontal apparatus.	Used for guided tissue regeneration procedures in periodontal defects to enhance regeneration of the periodontal apparatus.
Incorporates Same Basic Design	Yes	Yes
Utilizes Same Operating Principle	Cell occlusive Implantable Resorbable Hemostatic	Cell occlusive Implantable Resorbable Hemostatic
Incorporates Same Materials?	Yes, Type I and Type III Collagen Same Amount	Yes, Type I and Type III Collagen Same Amount
Sterilization Process	Gamma Irradiation	Gamma Irradiation
Biocompatible	Yes	Yes
Non-pyrogenic	Yes	Yes
Shelf Life	36 Months	36 Months
Thickness (dry)	Approx. 2 mm	Approx. 2.5-5 mm
Thickness (when placed over defect)	Approx. 1 mm	Approx. 1 mm

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 30 2008

Ed. Geistlich Soehne Ag Für 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: K073711
Trade/Device Name: MUCOGRAFT® Collagen Matrix
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: II
Product Code: NPL
Dated: May 22, 2008
Received: May 23, 2008

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K073711

Indications for Use

510(k) Number (if known): K073711

Device Name: MUCOGRAFT® Collagen Matrix.

Indications for Use: 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; guided tissue regeneration procedures in periodontal and recession defects.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _X_ OR Over-the-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

Susan Runner

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

510(k) Number: K073711