510(k) Summary

K061244

MUCOGRAFT®

JUN - 6 2006

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: April 21, 2006

2. DEVICE NAME

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

3. PREDICATE DEVICES

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

4. INTENDED USE

MUCOGRAFT® is recommended for:

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

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5. DEVICE DESCRIPTION

MUCOGRAFT® resorbable bilayer membrane for guided tissue and bone regeneration is physically identical to MUCOGRAFT® resorbable bilayer membrane (K012423), but labeled with an additional indication: guided tissue regeneration in periodontal defects. 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® resorbable bilayer membrane for guided tissue and bone regeneration is substantially equivalent to Geistlich's existing products BIO-GIDE® resorbable bilayer membrane for guided tissue and bone regeneration (subject to K960724; K042197; and K050446) and MUCOGRAFT® resorbable bilayer membrane (K012423). The only difference between the new product and the BIO-GIDE and MUCOGRAFT® products cleared previously via K042197 and K012423, respectively, is the proposed additional indication 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® (K012423).

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 was cleared for all of the indications for which BIO-GIDE® had been cleared at that time (pursuant to K960724). Per K042197, BIO-GIDE® was subsequently cleared for, among other uses, "guided tissue regeneration procedures in periodontal defects."

The following is a table comparing MUCOGRAFT® resorbable bilayer membrane to BIO-GIDE resorbable bilayer membrane for guided tissue and bone regeneration.

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Table 1: BIO-GIDE® Resorbable Bilayer Membrane (Predicate Device) vs. MUCOGRAFT® Resorbable Bilayer Membrane Comparison Chart

	BIO-GIDE® Resorbable Bilayer Membrane	MUCOGRAFT® Resorbable Bilayer Membrane
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	Yes, Type I and Type III Collagen
Sterilization Process	Gamma Irradiation	Gamma Irradiation
Biocompatible	Yes	Yes
Non-pyrogenic	Yes	Yes
Shelf Life	36 Months	36 Months

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

OCT 1 0 2007

Ed. Geistlich Soehne Ag Fur Chemische Industrie
C/O Mr. Peter S. Reichertz
Official Correspondent/U.S. Agent
Sheppard Mullin Richter & Hampton LLP
1300 I Street N.W. 11th Floor East
Washington, D.C. 20005-3314

Re: K061244
Trade Name: MUCOGRAFT® Resorbable Bilayer Membrane
for Guided Tissue and Bone Regeneration
Regulation Number: 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: 2
Product Code: NPL
Dated: May 2, 2006
Received: May 3, 2006

Dear Mr. Reichertz:

This letter corrects our substantially equivalent letter of June 6, 2006.

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 (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 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 continue 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) 276-0115. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.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

1906 - 2006
FDA
Centennial

Protecting and Promoting Public Health

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Indications for Use

510(k) Number (if known): _____

Device Name: MUCOGRAFT® Resorbable Bilayer Membrane for Guided Tissue and Bone Regeneration.

Indications for Use: Simultaneous use of GBR-membrane (MUCOGRAFT) and implants; augmentation around implants placed in immediate extraction sockets; augmentation around implants placed in delayed extraction sockets; localized ridge augmentation for later implantation; alveolar ridge reconstruction for prosthetic treatment; filling of bone defects after root resection; cystectomy, removal of retained teeth; guided bone regeneration in dehiscence defects; guided tissue regeneration procedures in periodontal 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 Runyon

...ion Sign-Off)
...n of Anesthesiology, General Hospital,
...ion Control, Dental Devices
...Number K061244