

NOV 15 2004

K042197

510(k) Summary

BIO-GIDE®

1. SPONSOR

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

Contact Person: Peter S. Reichertz, (202) 408-9222
Date Prepared: August 12, 2004

2. DEVICE NAME

Proprietary Name: BIO-GIDE®
Common/Usual Name: Resorbable Bilayer Membrane for Guided Tissue and Bone
Regeneration
Classification Name: Dental Bone Grafting Material

3. PREDICATE DEVICES

BIO-GIDE® (K960724)

BioMend Extend® (K99216)

4. INTENDED USE

BIO-GIDE® is recommended for:

- Simultaneous use of GBR-membrane (BIO-GIDE®) 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.

5. DEVICE DESCRIPTION

BIO-GIDE® resorbable bilayer membrane for guided tissue and bone regeneration is physically identical to BIO-GIDE® (K960724), but labeled with an additional indication; guided tissue regeneration in periodontal defects. BIO-GIDE® is a pure collagen membrane obtained by a standardized controlled manufacturing process. The collagen is extracted from veterinary certified pigs and is carefully purified to avoid antigenic

reactions. BIO-GIDE® is sterilized in double blisters by gamma irradiation. BIO-GIDE® has a bilayer structure. The porous surface - facing the bone - allows the ingrowth of bone forming cells. The dense surface - facing the soft tissue - prevents the ingrowth of fibrous tissue into the bone defect. The membrane is made of collagen type I and type III without further cross-linking or chemical treatment.

6. BASIS FOR SUBSTANTIAL EQUIVALENCE

BIO-GIDE® resorbable bilayer membrane for guided tissue and bone regeneration is substantially equivalent to Geistlich's existing product, BIO-GIDE® (K960724), and BioMend Extend™ (K992216). The only difference between the new product and the BIO-GIDE® product previously cleared is the additional indication for guided tissue regeneration in periodontal defects. ("GTR"). The following is a table comparing BIO-GIDE® to BioMend Extend™, a collagen membrane cleared for GTR.

Table I: BioMend Extend™ Absorbable Collagen Membrane (Predicate Device) vs. BIO-GIDE® Resorbable Bilayer Membrane Comparison Chart

	BioMend Extend™ Absorbable Collagen Membrane	BIO-GIDE® 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.
Incorporate Same Basic Design	Yes	Yes
Utilizes the Same Operating Principle	Cell occlusive Implantable Resorbable Hemostatic	Cell occlusive Implantable Resorbable Hemostatic
Incorporates Same Materials?	Yes, Type I Collagen	Yes, Type I and Type III Collagen
Sterilization Process	ETO	Gamma Irradiation
Biocompatible	Yes	Yes
Non-pyrogenic	Yes	Yes
Shelf Life	24 Months	36 Months

Studies Submitted:

Romagna-Genon, C., Comparative Clinical Study of Guided Tissue Regeneration with a Bioabsorbable Bilayer Collagen Membrane and Subepithelial Connective Tissue Graft, *J. Periodontol*, 72 (9), p. 1258-1264. (2001)

Lekovic, V., et. al., Effectiveness of a Combination of Platelet-Rich Plasma, Bovine Porous Bone Mineral and Guided Tissue Regeneration in the Treatment of Mandibular Grade II Molar Furcations in Humans, *J. Clin. Periodontol*, (30), p. 746-51. (2003)

Houser, B.E., et. al., Clinical Evaluation of Anorganic Bovine Bone Xenograft with a Bioabsorbable Collagen Barrier in the Treatment of Molar Furcation Defects, *The Int'l J. of Periodontics & Restorative Dentistry*, 21(2), p. 161-69. (2001)

Camargo, P.M., et. al., A Controlled Re-Entry Study on the Effectiveness of Bovine Porous Bone Mineral Used in Combination with a Collagen membrane of Porcine Origin in the Treatment of Intrabony Defects in Humans, *J. Clin. Periodontol* (27), p. 889-896. (2000)

Sculean, A., et. al., Healing of Intrabony Defects Following Treatment with a Bovine Derived Xenograft and Collagen Membrane, *J. Clin. Periodontol* (30), p. 73-80. (2003)

Tonetti, M.S., et. al., Clinical Outcomes Following Treatment of Human Intrabony Defects with GTR/Bone Replacement Material or Access Flap Alone, *J. Clin. Periodontol* (To Be Published)

Camelo, M., Nevins, M.L., et. al., Clinical, Radiographic, and Histologic Evaluation of Human Periodontal Defects Treated with BIO-OSS® and BIO-GIDE®, *The Int'l J. of Periodontics & Restorative Dentistry*, 18(4), p. 321-331. (1998)

Camelo, M., Periodontal Regeneration with an Autogenous Bone-BIO-OSS® Composite Graft and a BIO-GIDE® Membrane, *The Int'l J. of Periodontics & Restorative Dentistry*, 21(2), p. 109-119. (2001)

Yamada, Satoru, Effect of Porous Xenographic Bone Graft with Collagen Barrier Membrane on Periodontal Regeneration, *The Int'l J. of Periodontics & Restorative Dentistry*, 22(4), p. 389-397. (2002)

Nevins, M.L., et. al., Evaluation of Periodontal Regeneration Following Grafting Intrabony Defects with BIO-OSS® Collagen: A Human Histologic Report, *The Int'l J. of Periodontics & Restorative Dentistry*, 23(1), p. 9-17. (2003)



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Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

Ed. Geistlich Soehne Ag Fur Chemische Industrie
C/O Mr. Peter S. Reichertz
Official Correspondent/U.S. Agent
Sonnenschein Nath & Rosenthal LLP
1301 K Street NW, Suite 600
Washington, D.C. 20005

Re: K042197
Trade Name: BIO-GIDE® 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: August 12, 2004
Received: August 18, 2004

Dear Mr. Reichertz:

This letter corrects our substantially equivalent letter of November 15, 2004.

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.

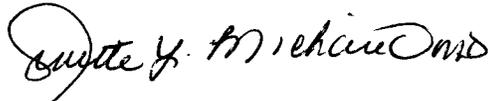
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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" (21 CFR 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



Protecting and Promoting Public Health

K042197

Indications for Use

510(k) Number (if known): K042197

Device Name: BIO-GIDE® Resorbable Bilayer Membrane for Guided Tissue and Bone Regeneration.

Indications for Use: Simultaneous use of GBR-membrane 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.

Susan Punor

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

510(k) Number: K042197

Prescription Use X

AND/OR

Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D)

(21 CFR 801 Subpart C)

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NEEDED)