K050446

510(k) Summary

AUG 9 - 2005

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: February 18, 2005

2. DEVICE NAME

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

3. PREDICATE DEVICES

BIO-GIDE® - K960724 and K042197

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. 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 K042197. The only difference between the new product and the BIO-GIDE® product previously cleared is the addition of heating step of 70°C for at least 30 minutes. This additional heating has been required by the Animal and Plant Health Inspection Service of the United States Department of Agriculture as assurance that the organisms responsible for Classical Swine Fever and Swine Vesicular Disease have been destroyed as a condition of importation of the products.

The revised manufacturing process has been validated and tests have been done that confirm that the additional heating step does not affect the final product and that, as such, it is substantially equivalent to the previously cleared predicate product.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

OCT 10 2007

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

Re: K050446
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: July 11, 2005
Received: July 12, 2005

Dear Mr. Reichertz:

This letter corrects our substantially equivalent letter of August 9, 2005.

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

Protecting and Promoting Public Health

Indications for Use

510(k) Number (if known): K050446

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.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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

510(k) Number: K050446