4/9/99

K990363

Summary of Safety and Effectiveness Information *Premarket Notification, Section 510(k)*	SAMYANG CORPORATION DECEMBER 1998

Regulatory Authority: Safe Medical Devices Act of 1990, 21 CFR 807.92

1. ***Trade Name:***

BioMesh® Biodegradable GTR Barrier

Common Name(s): GTR Barrier

Classification Name(s): Unclassified device

2. ***Establishment Name & Registration Number:***

Name: SAMYANG CORPORATION
Number: Pending

3. ***Classification:***

Device Class: II
Classification Panel: Dental
Product Code(s): LYC

4. ***Equivalent Predicate Device:***

SAMYANG CORPORATION believes that ***BioMesh® Biodegradable GTR Barrier*** is substantially equivalent to Resolut Regenerative Material as characterized in K932866, K962624 and K973594.

1. Gore Resolut Regenerative Material, K932866, K962624 & K973594

Comparison of ***BioMesh® Biodegradable GTR Barrier*** brand GTR barrier to the predicate device(s) identified above based on available labeling, promotional materials, comparison testing, demonstrates the substantial equivalence of ***BioMesh® Biodegradable GTR Barrier***.

5. ***General Device Description:***

BioMesh® Biodegradable GTR Barrier is provided as a single membrane type, but in a variety of precut shapes and sizes. **Shapes and sizes.** As noted on the graphic representation at the left, five different shapes are offered. The ***BioMesh® Biodegradable GTR Barrier*** is shape optimized to provide a ready made pattern well suited to the selected operative site needing a minimum of surgeon modification. If desired, the surgeon can trim any of the available shapes to fit unique or unusual circumstances. The ***BioMesh® Biodegradable GTR Barrier*** is made from polyglycolic acid with a coating of polylactic acid + polylactic glycolic acid copolymer. The membrane is constructed with interconnective pores with an embossed surface.

6. ***Applicant Name & Address:***

SAMYANG CORPORATION
263 Yeonji-dong, Chongno-gu
Seoul 110-725, Korea

7. *Company Contact:*

Mr. Dong-Kee Yoo
SAMYANG CORPORATION
263 Yeonji-dong, Chongno-gu
Seoul 110-725, Korea
Tel. 011.82.2.740.7296
Fax 011.82.2.743.6626

8. *Submission Correspondent:*

Mr. David W. Schlerf
Buckman Company, Inc.
200 Gregory Lane, Suite C-100
Pleasant Hill, CA 94523-3389
925.356.2640 - 925.356.2654 - fax

9. *Performance Standards:*

United States Food and Drug Administration mandated performance standards for this device do not exist. Various voluntary performance standards are utilized. Voluntary standards utilized include U.S.P., ASTM, Standard Operating Procedures, vendor & process certification and qualification procedures, Quality Systems Regulations, ISO materials standards and ISO 9000 series quality regulations.

10. *Storage, Packaging & Sterilization Information:*

Packaging. Packaging should be inspected on arrival for evidence of shipping damage. Damaged packaging may indicate the presence of unsafe product and it should not be used until carefully inspected. If the package or product is damaged, the product should not be used and should be returned. Once opened, the product should never be resterilized or reused. **Storage.** Product must be handled, stored and opened in such a way that it is protected from inadvertent damage or contamination. Rotate stock and observe shelf life dates. Discard when outdated or damaged. When used, the product must be placed into use following accepted surgical sterile technique. **Sterilization.** ***BioMesh®*** ***Biodegradable GTR Barrier*** is supplied ***"STERILE"*** and is terminally EtO sterilized in accordance with accepted standards.

11. *Summary Comparison Table:*

FEATURE	*BioMesh*	*Resolut*	SE?
Indications for Use:	Two or three wall vertical defects,Class II furcations, Circumferrential defects, Recession type defects, Dehisence defects associated with dental implants	SAME	YES
Material:	polyglycolic acid with a coating of polylactic acid + polylactic glycolic acid copolymer	Equivalent	YES
Structure:	microporous membrane made of biodegradable polyglycolide, polylactide and d,l-lactide/glycolide copolymer. The membrane is made up of interconnective pores with an embossed surface.	Non-woven membrane yes, no interconnecting pores, no embossing	Equivalent
Tissue Integration:	Test result score 115	Test result score 110	YES
Biocompatability:	Good	Good	YES
Toxicity:	Good	Good	YES
Stability:	5 Years	5 Years	YES
Clinical Data:	Good	Good	YES
Manufacturer:	SAMYANG	GORE	YES
Product Code:	LYC	SAME	YES
K - Number:	Pending	K932866, K962624 & K973594	YES

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

OCT 10 2007

Samyang Corporation
C/O Mr. David W. Schlerf
Buckman Company, Incorporated
200 Gregory Lane, Suite C-100
Pleasant Hill, California 94523-3389

Re: K990363
Trade Name: BioMesh® Biodegradable GTR Barrier
Regulation Number: 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: 2
Product Code: NPK
Dated: December 28, 1998
Received: February 5, 1999

Dear Mr. Schlerf:

This letter corrects our substantially equivalent letter of April 9, 1999.

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

510(k) Number : K990363

Device Name(s): ***BioMesh® Biodegradable GTR Barrier***

Intended Use(s) of the Device:

BioMesh® Biodegradable GTR Barrier is intended for use in the surgical management and treatment of periodontal defects to aid in the regeneration and integration of tissue components in guided tissue regeneration procedures.

Indications for Use:

BioMesh® Biodegradable GTR Barrier is indicated for use in the treatment of the following specific conditions:

1. Two or three wall vertical defects.
2. Class II furcations.
3. Circumferrential defects.
4. Recession type defects.
5. Dehisence defects associated with dental implants

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K990362

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109) (Optional format 1-2-96)