



OCT 10 2007

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville, Maryland 20850

Mr. Bruce G. Ruefer  
President  
American Custom Medical, Company  
2430 N. 7<sup>th</sup> Avenue, Suite 4  
Bozeman, Montana 59715

Re: K965205  
Trade Name: TefGen-LS™  
Regulation Number: 872.3930  
Regulation Name: Bone Grafting Material  
Regulatory Class: 2  
Product Code: NPK  
Dated: March 12, 1997  
Received: March 14, 1997

Dear Mr. Ruefer:

This letter corrects our substantially equivalent letter of April 30, 1997.

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*

K965205

APR 30 1997

## TefGen-LS™ 510(k) SUMMARY OF SAFETY AND EFFICACY

Prepared by: Bruce G. Ruefer, President

Date: December 20, 1996

Classification Name: Augmentation Membrane, 76LYC

Common/Usual Names: Barrier Membrane; Guided Tissue Membrane; or GTR Membrane.

Proprietary Name: TefGen-LS™ Guided Tissue Membrane

Establishment Reg. No. 9006936

Classification: Class II

Performance Standards: Not Applicable.

Substantial Equivalence: The non-absorbable augmentation membrane is manufactured by American Custom Medical and is equivalent in function to the augmentation membranes manufactured and marketed by both American Custom Medical and W.L. Gore which are currently on the market.

Product Description & Intended Use: TefGen-LS membrane is a 100% PTFE non-absorbable guided tissue membrane. TefGen-LS is an implant material which is intended to be used as a temporary space making barrier over bone or other tissue. The material is easily trimmed to a variety of shapes as required by specific cases.

Comparative Technological Characteristics: TefGen-LS is a biocompatible 100% PTFE membrane, is non-resorbable, is stiff enough to create a space, and is supple enough to be formed over the margins of a defect; as are the predicate devices.

Safety & Efficacy: TefGen-LS is composed of 100% polytetrafluoroethylene or PTFE. PTFE is the most inert polymer known at this time. PTFE's use as an implant material in the cardiovascular area is well substantiated with over 3,000,000 PTFE vascular grafts implanted to date. Many other configurations of PTFE devices are marketed including soft tissue and cardiovascular PTFE patches, PTFE suture, PTFE barrier membranes, and PTFE ear implant devices.

PTFE has been found to pass biocompatibility assays including U.S.P. Class VI, carcinogenicity studies, hemocompatibility studies, and others. PTFE has been proven many times over to be non-reactive to body fluids and tissues making it a material of choice for biomaterial applications.

## TefGen-LS™ 510(k) SUMMARY OF SAFETY AND EFFICACY (cont)

### Literature:

ACM PTFE has been found to function as an acceptable augmentation membrane as noted in the following articles:

"The Use of High-Density Polytetrafluoroethylene Membrane to Treat Osseous Defects: Clinical Reports", B. Bartee, D.D.S., *Implant Dentistry*, 4, 1995, pgs. 21-26.

"Evaluation of a Full Density Polytetrafluoroethylene (PTFE) Film to Promote Osteogenesis in the Rat Model", J. Carr, et.al., *Oral Implantology*, 21, 1995, pgs. 88-95.

"Influence of Three Membrane Types on Healing of Skull Lesions", B. Crump, et.al, presented at the 1995 IADR Annual Meeting, Singapore, June, 1995.

"The Influence of Three Membrane Types on Healing of Bone Defects", B. Crump, et.al., *Oral Surgery, Oral Medicine, Oral Pathology and Oral Radiology*, Oct. 1996, pgs. 365-374.

"High-density PTFE Membranes: Uses with Root-form Implants", J. Krauser, *Dental Implantology Update*, 7, pgs. 65-69, 1996.

*Clinical Research Associates Newsletter*, 20:4, February 1996.

### Conclusion:

The TefGen-LS membrane configuration is substantially equivalent to the currently marketed TefGen-FD membrane and currently marketed GORE-TEX augmentation membrane.