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TefGen™ 510(k) SUMMARY OF SAFETY AND EFFICACY

Prepared by:	Bruce G. Ruefer, President
Date:	November 18, 1996
Classification Name:	Augmentation Membrane, 76LYC
Common/Usual Names:	Barrier Membrane; Guided Tissue Membrane; or GTR Membrane.
Proprietary Name:	TefGen™ 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 non-reinforced (TefGen-FD) and TefGen reinforced (TefGen-RE) membranes are 100% PTFE non-absorbable guided tissue membranes. TefGen 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 conformable to a variety of shapes as required by specific cases.
Comparative Technological Characteristics:	TefGen 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 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™ 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 membrane configurations, non-reinforced (TefGen-FD) and reinforced (TefGen-RE), are substantially equivalent to the currently marketed TefGen-FD membrane and currently marketed GORE-TEX augmentation membrane.