K974752

MAR - 3 1998

510 (k) Summary

SUBMITTED BY:

M. K. Patterson, Jr. PhD
Sr Vice President
Regulatory Affairs
IMTEC Corporation
2401 North Commerce
Ardmore, Oklahoma 73401
(405) 223-4456

F.D.A Registration Number: 1645158
Owner / Operator Number: 9003407

Date Submitted: December 20 ,1997

CLASSIFICATION/COMMON OR USUAL NAME/ DEVICE NAME:

Classification Name: AUGMENTATION MEMBRANE, 76LYC.
Common/ Usual Name: GUIDED TISSUE MEMBRANE, PTFE.
Proprietary Name: IMTEC/ BIOBARRIER MEMBRANE (K950306 / K972240)

PREDICATE DEVICE:

Osteohealth, Bio-gide, K960724

DEVICE DESCRIPTION:

IMTEC/BIOBARRIER is a non-absorbable guided tissue membrane composed of 100% Polytetrafluoroethylene. It is provided in various dimensions and can be cut to a preferred shape or size The device will be marketed as a sterile device. It is available in either Porous (5 μ) or Non-Porous, "full density" PTFE.

INDICATIONS FOR USE:

IMTEC BioBarrier is a temporarily implantable material intended to be used as a space maintaining barrier over bone. It is intended for use in the oral cavity. The material is conformable to a variety of shapes as required for specific anatomical limitations.

The IMTEC BioBarrier is additionally indicated for:

- **simultaneous use of GBR-membrane (BioBarrier) and implants:**
- **augmentation around implants placed in immediate extraction sockets;**
- **augmentation around implants placed in delayed extraction sockets;**
- **localized ridge augmentation for later implantation.**

Because of its elasticity, the IMTEC BioBarrier should be used in combination with space-making bone graft materials, e.g., autogenous bone or bone substitutes.

PRINCIPLES OF OPERATION:

IMTEC/ BIOBARRIER is manufactured from biocompatable,100% PTFE. It has been demonstrated to serve as a temporary mechanical barrier to undesirable tissue growth into an osseous cavity. It is designed to be a passive barrier which reduces the migration of epithelial and gingival connective tissue into a bony repair site.The material is firm enough to provide sufficient mechanical support over a site while maintaining adequately supple characteristics during placement such that tissue compliance related problems are reduced.

CONTRAINDICATIONS:

It is critical that when used in dental implant repair applications that the implant is stable. It may NOT be used to stabilize a failed implant. Contraindications customary to the use of bone grafts and membrane techniques should be observed. These include, but are not limited to, current local infection, vascular impairment, uncontrolled diabetes, chronic high dose of steroids, clotting disorders, current anticoagulant therapy, etabolic bone disease, and other metabolic or systemic disorders which will affect bone or wound healing.

COMPLICATIONS:

Possible complications with any oral reconstructive surgery include infection, closure perforation, abcess formation, bone loss, pain, soft tissue irregularities, and additional complications associated with anesthesia and dental surgery. Specific to this surgery is augmentation material perforation or exfoliation. Depending on the type and severity of the complications the removal of the membrane may be indicated.

MATERIALS OF CONSTRUCTION:

IMTEC/ BIOBARRIER is constructed of 100% polytetrafluoroethylene (PTFE).

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS:

The uses of IMTEC/BIOBARRIER are similar to the currently marketed predicate devices which are used for Guided Bone Regeneration (GBR) in conjunction with endosseous dental implant placement and repair.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

OCT 10 2007

Mr. M.K. Patterson, Jr. Ph.D.
Sr. Vice President Regulatory Affairs
IMTEC Corporation
2401 North Commerce
Ardmore, Oklahoma 73401

Re: K974752
Trade Name: Imtec/Biobarrier Membrane
Regulation Number: 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: 2
Product Code: NPK
Dated: December 19, 1997
Received: December 19, 1997

Dear Dr. Patterson:

This letter corrects our substantially equivalent letter of March 3, 1998.

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

K974752

510(k) Number (if known): _____

Device Name: **IMTEC BIOBARRIER MEMBRANE**

Indications For Use:

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

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 K974752

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)