

K972240

AUG 26 1997

**SAFETY AND EFFECTIVENESS:
IMTEC/BIOBARRIER**

**Submitted by: M. K. Patterson, Jr., PhD
Sr. Vice President,
Regulatory Affairs**

A long history exists for the safe and effective use of some nonresorbable biocompatible synthetic materials when implanted into the human body. The material most documented as safe and effective is a polymer known as polytetrafluoroethylene or PTFE. This material, first patented in 1941 and better known as "TEFLON" is composed of long chains of linked Carbon-Fluoride units. Over 100 (1) to 150 (2) publications by independent researchers in peer-reviewed scientific journals have established the material as a suitable material for reconstructive surgical procedures such as cardiovascular and hernial patches, vascular grafts, sutures and periodontal repairs. In periodontal procedures a technique known as "Guided Tissue Repair (GTR)" was introduced in 1982 by Nyman, et al (3). They first described the use of nonresorbable "Millipore Filter" in the procedure. The GTR principle is based on the isolation of incised oral epithelial and gingival connective tissue from treated root surfaces or from Alveolar bone in the case of osseointegrated dental implants. In the latter case the isolation allows osteoblasts and endothelial cell to repopulate the wound, consequently enhancing the closure of a bony defect around the implant. PTFE membranes have subsequently been used with success to exclude those cells without osteogenic potential (4-6).

PERI-IMPLANT OSSEOUS REPAIRS:

In early studies using expanded PTFE membranes to cover implants, Becker, et al (7) placed implants in the mandible of dogs and created a defect by exposing threads of the implants. The implants were then covered with membrane. After 18 weeks the implants covered by the membranes showed marked bone growth when compared to controls. Similar techniques have proven successful in humans (8 - 11).

The aforementioned studies were conducted using an expanded (porous) form of PTFE. A recurring problem with porous PTFE has been that should primary closure of the tissue fail ,infection occurs, and the membrane must be prematurely removed. Bartee (12), suggested that "high density" PTFE (nonporous) membranes could be left exposed in the

oral cavity and promote the deposition of bone without compromising the bone grafting material. Subsequent studies (13 - 15) comparing various membrane types have confirmed his observation.

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IMTEC Corporation
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Re: K972240
Trade Name: Imtec Biobarrier Membrane
Regulation Number: 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: 2
Product Code: NPK
Dated: June 10, 1997
Received: June 16, 1997

Dear Dr. Patterson:

This letter corrects our substantially equivalent letter of August 8, 2001.

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

510(k) Number (if known): K972240

Device Name: IMTEC BIOBARRIER MEMBRANE

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.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Pusner
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K972240

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use