



Memorandum

From: Reviewer(s) - Name(s) Robert S. Betz

Subject: 510(k) Number K974752

To: The Record - It is my recommendation that the subject 510(k) Notification:

- Refused to accept.
- Requires additional information (other than refuse to accept).
- Accepted for review 12-23-97
- Is substantially equivalent to marketed devices.
- NOT substantially equivalent to marketed devices.
- Other (e.g., exempt by regulation, not a device, duplicate, etc.)

- Is this device subject to Postmarket Surveillance? YES NO
- Is this device subject to the Tracking Regulation? YES NO
- Was clinical data necessary to support the review of this 510(k)? YES NO
- Is this a prescription device? YES NO
- Was this 510(k) reviewed by a Third Party? YES NO

This 510(k) contains:

Truthful and Accurate Statement Requested Enclosed
(required for originals received 3-14-95 and after)

A 510(k) summary OR A 510(k) statement

The required certification and summary for class III devices N/A

The indication for use form (required for originals received 1-1-96 and after)

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

- No Confidentiality
- Confidentiality for 90 days
- Continued Confidentiality exceeding 90 days

Predicate Product Code with class and tier: Additional Product Code(s) with panel (optional):

76 LYC (unclassified)

Review: Susan Pinner
(Branch Chief)

DEDA
(Branch Code)

3/3/98
(Date)

Final Review: _____
(Division Director)

3/3/98
(Date)

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INTEROFFICE MEMORANDUM


TO: THE RECORD
FROM: ROBERT S. BETZ DDS
SUBJECT: K974752
IMTEC BIOBARRIER MEMBRANE
DATE: 2 MARCH, 1998

CONTACT: M. K. PATTERSON
IMTEC CORP.
ARDMORE, OKLAHOMA

Imtec Corporation has submitted the third in a series of premarket notification submissions for its polytetrafluoroethylene (PTFE) membrane, Biobarrier. This is an additional indication for use submission for a 76 LYC (unclassified) membrane previously cleared under K972240. Imtec markets a PTFE membrane device (K950306), which is an expanded PTFE, having a pore size of 5 μ . The K972240 Imtec PTFE membrane device is the same membrane described in the present submission, and is considered a non-porous form, having a pore size of 0.2 μ . These devices have been cleared for use in periodontal defects.

The sponsor claims that the Imtec Biobarrier may be used in immediate extraction sites, for ridge augmentation in preparation for implant placement, and concurrently with initial implant fixture placement in immediate extraction sockets. These claims have been made for Bio Gide[®], a resorbable porcine collagen membrane, which has been cleared under K960724, and is legally marketed at this time. The material composition and manufacture, of Imtec's Biobarrier are different from Bio Gide[®] membrane, but they have the same indications for use. Bio Gide[®] does not need to be removed; it is resorbed by the body. However, Biobarrier must be surgically removed. The different recovery mechanisms (surgical removal of the Imtec membrane vs. Bio Gide[®] membrane resorption) do not raise new questions of safety or effectiveness.

To demonstrate that the membranes are similar, the sponsor submitted three studies; two clinical studies, and one animal study. Experimental animals were followed for three months after crestal placement of implant fixtures. The implant fixtures studied, demonstrated a non-clinically significant amount of bone growth. Controls (no membranes), lost non-clinically significant amounts of bone. The difference between



the two averages as clinically significant, but not very substantial. There was no loading of the implants placed in this study, and the post operative healing time was too short to draw meaningful conclusions.

One of the clinical studies evaluated the use of the Imtec Biobarrier concurrent with implant fixture placement. The other study evaluated the use of the Imtec Biobarrier in what was described as "localized failing" but non-mobile implants. This means that there were fixture threads exposed. None of the implants in either study were evaluated after being loaded, and no histology was submitted. Conclusions drawn from these clinical studies are not based on well constructed protocols, and cannot not be taken at full face value. In addition, repair of "locally failing" implants, was not convincingly demonstrated. On 24 February, 1998, M. K. Patterson of Imtec indicated that the sponsor makes no claims for repair of locally failing implants. Imtec wishes only to make the same claims made by Geistlich Pharma for Bio Gide®

These three studies, when considered together, do show that the Imtec Biobarrier appears to perform in a manner similar to the Bio Gide® barrier membrane. Even though not demonstrated in these clinical studies, bone regenerated by the Imtec membrane should be similar to bone regenerated by the Bio Gide® membrane. The reason for this is that the underlying bone biology for both processes is the same. It is quite probable that claims made by the sponsor, although poorly substantiated, are most likely reasonable.

Recommendation: Substantially Equivalent (SE)

The Imtec device has not changed from the submission of K972240 in any manner, with the exception of the addition of the above mentioned indications for use. This device and the Bio Gide® device are similar in indications for use and technique for implantation. They are different with respect to physical properties, chemical composition and the need for removal. The response to their use is similar. The differences mentioned above do not raise new questions of safety or effectiveness. Their similarities indicate that these devices should be substantially equivalent for claimed uses. It is therefore recommended that the Imtec Biobarrier be found substantially equivalent to legally marketed devices.



Robert S. Betz DDS

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION


K974752

Reviewer: Robert S. Betz DDS

Division/Branch: DDIGD/DEDB

Device Name: Biobarrier Membrane

Product To Which Compared (510(K) Number If Known): Imtec Biobarrier, (K950306); Imtec Corp. Biobarrier, (K972240); Bio Gide (K960724), Geistlich Pharma

	YES	NO	
1. Is Product A Device	X		If NO - Stop
2. Is Device Subject To 510(k)?	X		If NO - Stop
3. Same Indication Statement?	X		If YES - Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES - Stop NE
5. Same Technological Characteristics?	X		If YES - Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?			If YES - Go To 8
7. Descriptive Characteristics Precise Enough?	X		If NO - Go To 10 If YES - Stop SE
8. New Types Of Safety Or Effectiveness Questions?			If YES - Stop NE
9. Accepted Scientific Methods Exist?			If NO - Stop NE
10. Performance Data Available?			If NO - Request Data
11. Data Demonstrate Equivalence?			Final Decision: SE 

1. Intended Use: See review, above.

2. Device Description: This is a microporous PTFE membrane used to aid in the generation of bone in cases where there is insufficient bone for implant placement. It is also used for regeneration of alveolar bone lost due to disease or trauma. The device is presently on the market, and is similar to BioGide® in indications for use. This submission is for an additional indication for use. Is the device life-supporting or life sustaining? No. Is the device implanted (short-term or long-term)? Yes. Does the device design use software? No. Is the device sterile? Yes. Is the device for single use? Yes. Is the device for home use or prescription use? Rx use only. Does the device contain drug or biological product as a component? No. Is this device a kit? No.