JUN 1 2 2001

K010775

510 (k) SUMMARY

SUBMITTED BY:

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

(580) 223-4456

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

Date Submitted: March 12, 2001

CLASSIFICATION/COMMON OR USUAL NAME/ DEVICE NAME:

Classification Name: Unclassified Device.
Code:LYC
Common/ Usual Name:GTR
Proprietary Name: BioCELLECT™.

PREDICATE DEVICE:

Epi-Guide™ (K940643)

DEVICE DESCRIPTION:

BioCELLECT™ is composed of a porous structure of synthetic bioabsorbale compressed L (-) Lactide homopolymer fibers. The porous structure is designed to attach to surrounding soft tissue and inhibit epithelial migration during wound healing. It is a biocompatible, cell occlusive, clinically manageable device that allows for tissue integration without further surgical intervention.

INDICATIONS FOR USE:

BioCELLECT™ is a bioabsorbable implantable membrane intended for use in the surgical management and treatment of periodontal defects to aid in the regeneration and integration of tissue components in guided tissue regeneration procedures. It is also used as a membrane that provides a stable barrier for the containment of bone graft material.

PRINCIPLES OF OPERATION:

BioCELLECT™ is a homopolymeric resorbable membrane that provides a barrier for use in the surgical management and treatment of periodontal defects to aid in the regeneration and integration of tissue components in guided tissue regeneration procedures. The membrane retains its integrity for a period sufficient to prevent epithelial cellular invasion into the site while bone regeneration occurs. The membrane is then degraded through hydrolysis which cleaves the homepolymer into lactic acid oligomers of low molecular weight. The lactic acid oligemers are absorbed by the surrounding tissues and further hydrolyzed into lactic acid. Lactic acid in metabolized to carbon dioxide and water. BioCELLECT™ is composed of the natural L- isomer of lactic acid, therefore local inflammatory response is minimal. The use of this resorbable membrane eliminates further surgical intervention.

CONTRAINDICATIONS:

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 at the surgical site, uncontrolled diabetes, chronic high dose steroid therapy, clotting disorders, current anticoagulant therapy, metabolic bone disease, and other metabolic or systemic disorders which affect bone or wound healing.

COMPLICATIONS:

Possible complications with any oral reconstructive surgery include infection, closure perforation, abscess 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.

MATERIALS OF CONSTRUCTION:

BioCELLECT™ is composed of spun fibers of PURASORB PL™, a homopolymer of L(-) Lactide (M.W. 180,000) ,which are processed into a "nonwoven fabric" by TRANSOME, Inc., Pam Bay, Florida and then compressed into a 0.3mm thick membrane by a hot platen process by IMTEC-SWISS, Ardmore, OK.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS:

The design, material, configuration, method of sterilization and other technological characteristics of BioCELLECT™ is similar to the currently marketed predicate devices. A comparative in vitro study of the degradation of BioCELLECT™ to Epi-guide shows comparable degradation . The study was performed at the Department of Zoology under the direction of Dr. Barbara Mroczka under the auspices of the University of Oklahoma School of Dentistry. The results are shown in Enclosure VI.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 2 2001

Mr. M.K. Patterson
Senior Vice President
IMTEC Corporation
2401 North Commerce
Ardmore, Oklahoma 73401

Re: K010775
Trade Name: BioCELLECT™
Regulatory Class: Unclassified
Product Code: LYC
Dated: March 12, 2001
Received: March 14, 2001

Dear Mr. Patterson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does

not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K010775

Device Name: BioCELLECT™

Indications For Use:

BioCELLECT™ is a bioabsorbable implantable membrane intended for use in the surgical management and treatment of periodontal defects to aid in the regeneration and integration of tissue components in guided tissue regeneration procedures. It is also used as a membrane that provides a stable barrier for the containment of bone graft material.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional Format 1-2-96)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K010775