K982951

JUN 21 1999

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: August 20,1998

CLASSIFICATION/COMMON OR USUAL NAME/ DEVICE NAME:

Classification Name: Screw, fixation, intraosseous (ref: 21 CFR 8722.4880); Product Code: DZL
Common/ Usual Name: Membrane fixation pin.
Proprietary Name: IMTEC BioPin.

PREDICATE DEVICE:

LEADfix Bioresorbable Membrane Pin (K974392)
3I Bioresorbable Fixation Tack (K972480)
Synthes Fixation System (K974554)

DEVICE DESCRIPTION:

The IMTEC BioPin is a bioresorbable pin designed to fixate and stabilize bioresorbable barrier membranes in the oral cavity during the healing process following dental surgery. The pin provides an anchoring mechanism to resident and adjacent bone at the surgical site. The pin is fabricated from a bioresorable copolymer of L and DL lactide. The pin has a low profile, round, lens shaped head an a shaft with two circular ribs. It is provided in a sterile vial.

INDICATIONS FOR USE:

The resorbable IMTEC BioPin pin is intended to stabilize bioresorbable guided tissue regeneration membranes during the healing process by providing an attachment. Its use is intended to avoind a second stage surgery required to remove nonresorbable tacks and pins.

PRINCIPLES OF OPERATION:

The IMTEC BioPin is a bioresorbable pin used used to fix commercially available bioresorbable guided tissue regeneration membranes.

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. Specifically if allergies to polylactid and lactic acid is known .

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.

MATERIALS OF CONSTRUCTION:

IMTEC BioPin is molded from PURASORB PL, a 70/30 copolymer of L(-) Lactide/ DL-Lactide (Molecular Weight: 152,000) by IMTEC-SWISS, Ardmore, OK.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS:

The design, material, configuration, method of sterilization and other technological characteristics of IMTEC BioPin are similar to the currently marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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M.K. Patterson, Jr., Ph.D.
Sr. Vice President
Regulatory Affairs
IMTEC Corporation
2401 North Commerce
P.O. Box 1562
Ardmore, Oklahoma 73402 U.S.A

Re: K982951
Trade Name: IMTEC BioPin
Regulatory Class: II
Product Code: DZL
Dated: March 22, 1999
Received: March 23, 1999

Dear Dr. 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 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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" (21 CFR 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/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):_____

Device Name:IMTEC BioPin

Indications For Use:

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

_____ _____ _____ _____ _____ _____ _____

Concurrance of CDRH, Office of Device Evaluation (ODE)

Prescription Use___✓___ OR Over-The-Counter Use___
(Optional Format 1-2-96)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K982951