4/13/99

K990983

510 (k) Summary :IMTEC Sendax MDI

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: March 22,1999

CLASSIFICATION/COMMON OR USUAL NAME/ DEVICE NAME:

Classification Name: Splint, Endonic Stabilizing (CFR 872.3890)
Common/ Usual Name: Dental Anchor Post
Proprietary Name: IMTEC Sendax MDI™

DEVICE DESCRIPTION:

Self-tapping titanium screw, 1.8 mm in width by 13, 15and 18 mm lengths.

INDICATIONS FOR USE:

To provide immediate transitional splinting stability or ongoing fixation of new/ existing crown, bridge and denture instillations in partial or fully endentulous settings.

CONTRAINDICATIONS:

Contraindications customary to the placement of dental implants should be observed. These include, but are not limited to, current local infection, vascular impairment, uncontrolled diabetes, chronic high doses of steroids, clotting disorders, current anticoagulant therapy, metabolic bone disease, and other metabolic or systemic disorders which will affect bone or wound healing. Excessive loading or placement of implants in inadequate bone may result in fracture.

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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.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS:

Comparable biocompatabile titanium material, manufactur, sterilization methods, and intended application

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 13 1999

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

Re: K990983
Trade Name: Modification to IMTEC Sendax MDI
Regulatory Class: III
Product Code: DZE
Dated: March 22, 1999
Received: March 24, 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

4/12/99

990983
510(k) Number ~~972351~~

Device Name:IMTEC Sendax MDI

Indications For Use:
This device is a self- tapping titanium threaded screw indicated for intra-bony and inter-radicular transitional application, to permit immediate splinting stability and ongoing fixation of new or existing crown and bridge instillations, for full or partial edentulism, an employing minimally invasive surgical intervention.

Representative applications include the following:

* Temporary (transitional supports for fixed or removable implant-supported prosthesies while conventional implants are integrating.
* Stabilizing interim prostheses in graft sites and guided tissue regeneration applications to avoid iatrogenic damage to healing grafts, membranes or integrating implants.
* Introductory system for nervous or apprehensive potential patients, offering a simple methodology for testing out the actual "feel of bone anchored implants, without the major commitment to final restorations; or as an interim system for medical compromised, handicapped or terminally ill patients to enhance their comfort by maintaining a reasonable level of speech, mastication and general well-being, at modest cost levels.

(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 K990983

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