DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 0 3 2002

Mr. Brad Vance
Director, Regulatory Affairs & New Projects
IMTEC Corporation
2401 North Commerce
Ardmore, Oklahoma 73401

Re: K023067
Trade/Device Name: IMTEC Sendax MDI ORTHO
Regulation Number: 872.3640
Regulation Name: Endosseous Implant
Regulatory Class: III
Product Code: DZE
Dated: August 28, 2002
Received: September 16, 2002

Dear Mr. Vance:

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 application (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 such 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 begin 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 (301) 594-4613. 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 Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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 Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K02 3067

INDICATIONS FOR USE STATEMENT

Device Name: IMTEC Sendax MDI ORTHO

Indications for Use:

This device is a self-tapping titanium threaded screw indicated for long-term intra-bony applications, or as an inter-radicular transitional application.

This device will permit immediate splinting stability and long-term fixation of new or existing crown and bridge installations, for full or partial endentulism, and employment of minimally invasive surgical interventions.

Representative applications include the following:

- Temporary (transitional supports for fixed or removable implant-supported prosthesis 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 the actual "feel" of bone anchored implants, without a major commitment to final restorations.
- As an interim system for medically 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)

Prescription Use √ or Over the Counter Use ____
(Per 21 CFR 801.109)

Susan Runyon
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K023067