IMTEC CORPORATION

K081653

SEP 1 9 2008

Traditional 510 (k)
Premarket Notification

510(k) Summary (21 CFR 807.92 (a))

1. Submitter's Information

Name: IMTEC Corporation
Address: 2401 N. Commerce
IMTEC Plaza
Ardmore, OK 73401
Phone: 580-223-4456
Contact: Glenn Gee
Date Prepared: 30 May 08

2. Device Name

Proprietary Name: MDI MII One-Piece Implant, 2.9mm

Common name: Dental Implant

Device Classification Name: Endosseous Dental Implant

Regulation No: 872.3640

Class: II

Panel: Dental

3. Predicate Device (s):

Alpha Bio 3.0mm One-Piece Implant K063364

Zimmer® One-Piece Implant, 3.0mm, Straight K052997

IMTEC Sendax MDI and MDI Plus K031106

IMTEC Endure Implant System K030243

4. Device Description:

The IMTEC MDI MII 2.9mm one-piece implant is a one piece endosseous dental implant that is a combination of implant and abutment sections. The thread lengths are 10mm, 13mm, 15mm, and 18mm. The implant is composed of Titanium alloy. The MDI MII

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body has a thread design for bone compression and the implant tip is equipped with our patent pending auto advancing cutting threads similar to those found on the IMTEC Endure Implant system. The implant section surface is blasted & etched to facilitate osseointegration. In addition, the implant has micro-threads at the intra-osseous collar to preserve crestal bone. It has a transgingival collar 2mm in height that includes a platform switching groove for soft tissue stability. The Implant has two prosthetic head design options, O-ball and Tapered Abutment design. The O-ball head on the MDI MII is identical to the O-ball head on the IMTEC MDI implant. Both are designed for fixed and removable applications. The abutment portion of the MII implant is coated with Titanium Nitride.

5. Intended Use:

The MII Implant is intended to support single unit or multi-unit restorations in both long-term and temporary applications throughout the maxillary and mandibular arches. The MII implant is indicated for immediate loading when good primary stability is achieved. Additionally, this device will permit stability and long term fixation of upper and lower dentures in edentulous cases.

6. Comparison of Technological Characteristics

Substantial equivalence of the MDI MII One-Piece implant is based on:

1. Design similarities between the proposed MDI MII implant and currently marketed fixtures within the IMTEC MDI Dental Implant System.

2. The proposed and currently marketed devices are equivalent in terms of size, materials of construction, performance characteristics, and basic design.

The MDI MII has patent pending, auto advancing, cutting threads, similar to those found on the IMTEC Endure Implant line. The addition to the MDI MII of the auto advancing, cutting threads have no adverse affects on the performance or safety of the IMTEC MDI MII 2.9mm Implant as evaluated in the performance testing conducted by the University of Georgia. The same types of safety and effectiveness characteristics are inherent with each of the devices. The features detailed do not raise new questions related to safety or efficacy of the implant.

The MDI MII implant described in this submission is substantially equivalent to the predicate devices listed and provides the same or similar functions, as well as design and technological characteristics. The intended use, statement of indications, technological characteristics and testing of the IMTEC MDI MII implants support the claim of substantial equivalence.

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There are no unique applications, indications, materials or specifications presented above. Evidence of equivalence has been demonstrated through:

- IMTEC MDI MII intended use and indications for use were previously cleared by the FDA for the various predicate devices listed above.
- The technical characteristics of the IMTEC MDI MII are similar to those of the predicate device.
- Safety and performance testing.

Therefore, the IMTEC MDI MII Dental Implant system is substantially equivalent to its predicate devices as cited above and raises no new safety and/or effectiveness issues.

7. Performance Testing

Laboratory testing by the Medical College of Georgia was conducted to confirm device functionality and conformance to design input requirements.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Glenn Gee
Regulatory Affairs Manager
IMTEC Corporation
2401 North Commerce
Ardmore, Oklahoma 73401

Re: K081653
Trade/Device Name: MDI MII 2.9mm Implants
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: September 4, 2008
Received: September 8, 2008

Dear Mr. Gee:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Samuel Lin for

Chiu S. Lin, Ph. D
Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K081653

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Indications for Use

510(k) Number (if known): MDI MII 2.9 mm Implants

Device Name: _____

Indications for Use:

The MII Implant is intended to support single or multi-unit restorations in both long-term and temporary applications throughout the maxillary and mandibular arches. The MII implant is indicated for immediate loading when good primary stability is achieved. Additionally, this device will permit stability and long term fixation of upper and lower dentures in edentulous cases.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

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

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