K083586

1 of 2

APR 2 9 2009

510(K) Summary

Submitter
Dentis Co., Ltd.
Shim Gi Bong
#951, Woram-Dong, Dalseo-Gu,
Daegu, South Korea
Phone: 82-53-589-3530
Fax: 82-53-583-2806
Registration Number: 3007031098

Official Correspondent
Kodent Inc.
Jung Bae Bang
13340 E. Firestone Blvd. Suite J
Santa Fe Springs, CA 90670
Email: kodentinc@kodent.co.kr
Phone: 562-404-8466
Fax: 562-404-2757

Device Information

Product Name: I-Fix System

Common Name: Endosseous Dental Implant

Classification Name: Implant, Endosseous, Root-Form

Product Code: DZE

Regulation Number: 872.3640

Device Class: Class II

General Description

The I-FIX System is mini implant system, which serves temporary support for provisional prosthetic device during the healing phase of permanent endosseous dental implants. The I-FIX System is comprised in diameter of 2.0 - 3.0mm and range from 10 - 16 mm and is made of CP Titanium grade 4. The surface treatment of I-Fix System is of R.B.M (Resorbable Blasting Media).

Indication for Use

The I-FIX System are intended to load immediately in partially or fully edentulous manidibles and maxillae to serve as temporary support for provisional prosthetic device during the healing phase of permanent endosseous dental implants.

K083586 2 of 2

Materials

This device are manufactured from TI6Al-4V ELI alloy following ASTM and ISO standards.

Predicate Devices

The subject device is substantially equivalent to the following predicate devices:

- Intermezzo™ Implant System (K051018) manufactured by Megagen Implant Co., Ltd.

Comparison to Predicate Devices

Testing and other comparisons have established that the subject of I-Fix System is substantially equivalent in design, materials, indications and intended use, packaging, labeling, and performance to other predicate devices of the type currently marketed in the U.S.

Performance Data

All of the data consistent with the recommendations in the FDA guidance document Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments, May 12, 2004, mechanical testing of the implants demonstrated that the I-Fix System possess mechanical strength at least equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Dentis Company, Limited
C/o Mr. Jung Bae Bang
Kodent, Incorporated
13340 East Firestone Boulevard
Suite J
Santa Fe Springs, California 90670

APR 2 9 2009

Re: K083586
Trade/Device Name: I-Fix System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: April 13, 2009
Received: April 13, 2009

Dear Mr. Bang:

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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

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 the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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,

Susan Runner, D.D.S., MA
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K083586 1 of 1

Indication for Use

510(K) Number (if known):

Device Name: I-Fix System

Indication for Use:

The I-FIX System are intended to load immediately in partially or fully edentulous manidibles and maxillae to serve as temporary support for provisional prosthetic device during the healing phase of permanent endosseous dental implants.

Prescription Use X AND/OR Over-The-Counter _____

(Part 21 CFR 801 Subpart D) (Per 21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for MSR

Page 1 of 1

...n Sign-Off)

...sion of Anesthesiology, General Hospital

...fection Control, Dental Devices

...0(k) Number: K083586