APR 20 2009

K090049

510(K) Summary

Submitter
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Device Information

Product Name: Atlas Implant System - Mini Plus

Common Name: Endosseous Dental Implant

Classification Name: Implant, Endosseous, Root-Form

Product Code: DZE

Regulation Number: 872.3640

Device Class: Class II

Device Description

The Atlas Implant System - Mini Plus is a dental implant made of titanium metal intended to be surgically placed in the bone of the upper and / or lower jaw arches. This system is similar to other commercially available products based on the intended use, the technology used, the claims, the material composition employed and performance characteristics.

Indication for Use

The Atlas Implant System - Mini Plus is 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.

Materials

These devices are manufactured from CP Titanium Grade 4 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.
- IMTEC Sendax MDI and MDI Plus (K031106) manufactured by IMTEC Corporation.
- Maximus™ OS Implant (K041938) manufactured by BioHorizons Implant Systems, Inc.

Comparison to Predicate Devices

Testing and other comparisons have established that the subject of Atlas Implant System - Mini Plus 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 Atlas Implant System - Mini Plus 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

APR 2 0 2009

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

Re: K090049
Trade/Device Name: Atlas Implant System –Mini Plus
Regulation Number: 21 CFR 872.3640
Regulatory Class: II
Product Code: DZE
Dated: April 15, 2009
Received: April 15, 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.

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) 276-0100. 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., M.A.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(K) Number (if known): K090049

Device Name: Atlas Implant System - Mini Plus

Indication for Use:

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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)

Kai Mulley for MSP

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

510(k) Number: K090049