K100850

510(K) Summary

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DEC 20 2010

Device Information

Device Classification

Trade Name: Cowell Implant System

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 Cowell Implant System 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 Cowell Implant System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. This system is not intended for immediate loading.

The implants with diameters larger than 5.0mm are intended to be surgically placed in the maxillary or mandibular molar areas for the purpose of providing prosthetic support for dental

restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. These implants are intended to be used where smaller implants have failed.

Predicate Devices

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

- SQ IS System (K090825) manufactured by Neobiotech Co., Ltd.
- Rescue Implant System (K053353) manufactured by MegaGen Co., Ltd.

Comparison to Predicate Devices

The Cowell Implant system has a substantially equivalent intended use as the identified predicates (K090825, K053353). This dental implant system made of pure titanium and the surface has been treated with ASD. It is intended to be surgically placed in the bone of the upper or lower jaw arches. The 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.

The Cowell Implant systems are similar in fundamental scientific technology to the predicate devices (K090825, K053353) in that they all have been designed, manufactured and tested in compliance with FDA's Class II special controls guidance document root-form endosseous dental implants and endosseous dental implant abutment. The subject and predicate devices are similar in size, materials, surface treatment, and are sterilized via gamma irradiation. The Cowell Implant system and the predicates include instruments to assist with the implant procedure.

Conclusions

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification SQ IS system (K090825) and Rescue Implant system (K053353) concludes that the ball abutment is safe and effective and substantially equivalent to predicate devices as described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Cowellmedi Company, Limited
C/O Ms. Joyce Bang
Kodent Incorporated
325 N. Puente St. Unit B
Brea, California 92821

DEC 2 0 2010

Re: K100850
Trade/Device Name: Cowell Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: November 23, 2010
Received: December 9, 2010

Dear Ms. 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 note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K100850

Indication for Use

510(K) Number (if known):

DEC 20 2010

Device Name: Cowell Implant System

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)

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

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