K071148

FEB - 6 2008

510(K) SUMMARY

Atlas Implant Systems

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR & 807.93

14-1. Submitter	Cowell Medi Co., Ltd #155-4 Gamjeon-2Dong, Sasang-Gu, Busan, South Korea Phone: 82-51-312-2028 Fax : 82-51-316-2628
14-2. US Agent / Contact Person	Dr. Chang Dae Kyu 3340 E. Firestone Blvd. Suite J, Santa Fe Springs, CA 90670 Phone : 562-404-8466, Fax : 562-404-2757
14-3. Date Prepared	April 18, 2007
14-4. Device Name	ATLAS IMPLANT SYSTEMS
14-5. Classification Name	Endosseous Dental Implant System
14-6. Device Classification	Class II Dental Devices panel 21 CFR ξ 872.3640, Regulation Number:872-3640
14-7. Predicate Devices	ALLFIM IMPLANT SYSTEM(K050635)
14-8. Performance	Laboratory testing was conducted to determine device functionality and conformance to design input requirements.

14-9. Device Description

The Atlas Implant System includes a variety of precision-machined fixtures manufactured from titanium. These implants are surgically inserted into the upper and/or lower jawbone and serve as a replacement for a patient's tooth root providing a stable foundation for restorations.

14-10. Packing / Labeling / Product Information

In a clean room that is Class 10,000 or less, put the product into a capsule, and then put the capsule in a pet container, which is 45mm by 75mm, then sealed the pet container with PERFECSEAL CR27 1073B Coated Tyvek®.

14-11. Intended Use

Atlas Implant Systems are designed for use in dental implant surgery. They are intended for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including, cement retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. They are not intended for use of immediate loading.

14-12. Substantial Equivalence Comparison

TECHNOLOGICAL CHARACTERISTIC COMPARISON

	Subject Device	Predicate Device
Manufacturer	Cowell Medi Co. Ltd.	Cowell Medi. Co. Ltd.
Device Name	Atlas Implant System	Allfim Implant System
510(k) Number	N/A	K050635
Indications for Use	Mandible and Maxilla Endosseous Dental Implant & Accessories	Mandible and Maxilla Endosseous Dental Implant & Accessories
Material	Commercially pure titanium GR. 3 and GR.4	Commercially pure titanium GR. 4
Design	Internal, External and Submerged	External
Screw Threads	YES	YES
Implant Diameter (mm)	Internal Type: 3.5, 4.0, 5.0 mm External Type: 3.3, 4.0, 5.0 mm	External: 3.3, 4.0, and 5.0 mm

	Submerged Type: 3.5, 4.0, 5.0 mm	
Lengths (External)	8-14 mm	8-14 mm
Surface Treatment	ASD (Anodic Spark Deposition)	Machined
Gamma sterilized	YES	YES

Attachments

Screw-retained restoration system	YES	YES
Cemented restoration system	YES	YES
Overdenture restoration	YES	YES
Instruments (surgical and restorative)	YES	YES

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 6 2008

Cowell Medi Company, Limited
C/O Dr. Chang Dae Kyu
KoDent, Incorporated
13340 East Firestone Boulevard, Suite J
Santa Fe Springs, California 90670

Re: K071148
Trade/Device Name: Atlas Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: January 24, 2008
Received: January 25, 2008

Dear Dr. Kyu:

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 (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

K071148

Indication for Use

510(K) Number (if known): _____

Device Name: Atlas Implant System

Indications for Use:

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Prescription Use ___X___ AND/OR _____ Over – The-Counter Use

(Part 21 CFR 801 Subpart D) (Per 21 CFR 801.109)

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

Susan Runner

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

510(k) Number: K071148