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10. 510(K) SUMMARY

Cowell Medi Co., Ltd
Dong-Ju Bldg 2F 45-3
Gaya 1 Dong, Busanjin-Gu, 614-800
Busan city, South Korea
Phone : 82-51-314-2028
Fax : 82-51-314-2026

510(K) Summary

510(K) SUMMARY AND CERTIFICATION

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

10-1. Submitter	Cowell Medi Co., Ltd. Dong-Ju Bldg 2F 45-3 Gaya 1 Dong, Busanjin-Gu 614-800 Busan, South Korea Phone : 82-51-314-2028, Fax : 82-51-314-2026
10-2. US Agent / Contact Person	Dae Kyu Chang 13340 E. Firestone Blvd. Suites J Santa Fe Springs, CA 90670 Phone : 562-404-8466, Fax : 562-404-2757
10-3. Date Prepared	March 5, 2005
10-4. Device Name	ALLFIM IMPLANT SYSTEMS Atlas Fixtures and Atlas Shoulder Abutment Systems
10-5. Classification Name	Endosseous Dental Implant System
10-6. Device Classification	Class II Dental Devices panel 21 CFR ξ 872.3640 Regulation Number: 872.3640
10-7. Predicate Devices	BIOPLANT Implant Systems (K041655) & Branemark Systems (K925777, K925779, K961728, K971706)
10-8. Performance	Laboratory testing was conducted to determine device functionality and conformance to design input requirements.

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10-9. Device Description

Allfim Implant System is an integrated system of endosseous dental implants which designed to support prosthetic devices for partially or fully edentulous patients. Allfim Implant Systems (Atlas Fixtures and Atlas Shoulder Abutments) consists of two-stage, root-form dental implants, associated abutment systems, which provide the clinician with cement-retained, screw-retained and overdenture-type restorative options. The devices covered by this submission are Atlas Fixtures, and Atlas Shoulder Abutments which are placed into dental implant to provide support for prosthetic reconstruction.

10-10. Packing / Labeling / Product Information

Allfim Implant Systems (Atlas Fixtures and Atlas Shoulder Abutment Systems) will be packaged.

10-11. Intended Use

Allfim Implant Systems refer to sets of root form endosseous dental implants and compatible implant abutment systems. Allfim Implant Systems are designed for use in dental implant surgery and are intended to be used in a manor in which they (the implants) integrate with the bone (osseointegration). The Allfim Abutment Systems include various abutments designed to enable the implant process from healing thru final restoration. The Atlas Fixtures are part of the Allfim Implant Systems and they are intended to use for two-stage surgical procedures. They are used on upper and lower jaw to provide a means for prosthetic attachments to restore a patient's chewing function. The system is intended for immediate placement 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.

10-12. Substantial Equivalence Comparison

Allfim Implant Systems (Atlas Fixtures and Atlas Shoulder Abutment Systems) and predicate implants share a substantially equivalent intended use. The

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BIOPLANT Implant Systems (Implants and Abutments Systems) (K041655), Branemark Systems (K925777, K925779, K961728, K971706), and Allfim Implant Systems (Atlas Fixtures and Atlas Shoulder Abutment Systems) are similar in fundamental scientific technology in that they are all threaded, root form implants constructed of titanium with roughened surfaces. The subject and predicate devices are similar in size and materials. All three systems offer abutment systems for cement-retained, screw-retained and overdenture restorations as well as associated accessories and instruments. When compared with the predicate devices, no new questions of safety or effectiveness have been raised for the Implant system.

10-13. Conclusion

The data submitted in this 510(K) notification is to legally sale the following devices in U.S. market:

- Atlas Internal Fixture (Regular), 4.0mm, 1.8mm and 2.4mm Collar Height
- Atlas Internal Fixture (Wide), 5.0mm, 1.8mm and 2.4mm Collar Height
- Atlas Internal Abutments – Regular
  – Wide
- Atlas External Fixture (Narrow), 3.3mm, 1.6mm Collar Height
- Atlas External Fixture (Regular), 4.0mm, 1.6mm Collar Height
- Atlas External Fixture (Wide), 5.0mm, 1.6mm Collar Height
- Atlas External Abutments – Narrow
  – Regular (Regular Neck, Wide Neck)
  – Wide
- Atlas Submerged Fixture (Regular), 4.0mm
- Atlas Submerged Fixture (Wide), 5.0mm
- Atlas Submerged Abutments – Regular
  – Wide

The Allfim Implant Systems (Atlas Fixtures and Atlas Shoulder Abutment Systems) are substantially equivalent to the legally marked products such as BIOPLANT Implant Systems (Implants and Abutment Systems) (K041655) and Branemark Systems (K925777, K925779, K961728, K971706).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 8 2005

Cowell Medi Company Limited
C/O Ms. Dae Kyu Chang
13340 E. Firestone Boulevard, Suite J
Santa Fe Springs, California 90670

Re: K050635
Trade/Device Name: Allfim Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Implant
Regulatory Class: II
Product Code: DZE
Dated: June 28, 2005
Received: June 30, 2005

Dear Ms. Chang:

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.

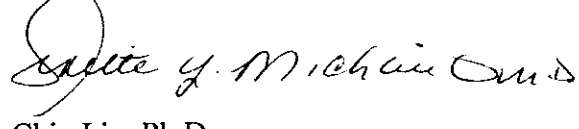
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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

Indications for Use

510(k) Number (if known): k050635

Device Name : AllFIM IMPLANTN SYSTEM

(Atlas Fixtures and Atlas Shoulder Abutment Systems)

Indications for Use:

Allfim Implant System is an integrated system of endosseous dental implants which designed to support prosthetic devices for partially or fully edentulous patients.

Allfim Implant Systems (Atlas Fixtures and Atlas Shoulder Abutments) consists of two-stage, root-form dental implants, associated abutment systems, which provide the clinician with cement-retained, screw-retained and overdenture-type restorative options.

The devices covered by this submission are Atlas Fixtures, and Atlas Shoulder Abutments which are placed into dental implant to provide support for prosthetic reconstruction.

The non-hexa-shoulder abutment is designed for single crown use only. The hexa-shoulder abutment is designed for bridge use only

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)

Susan Runner

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

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