14. 510(K) PREMARKET NOTIFICATION SUMMARY

14.1 Submitter:

Mega'Gen Co., Ltd.
114-8, Eupchun-Ri, Jain-Myun,
Gyeongsan, Gyeongbuk
South Korea
Phone: 82-53-857-5770, Fax : 82-53-857-5432

14.2 US Agent/Contact:

Kodent Inc. (PhD. Steve Chang)
13340 E. Firestone Blvd. Suite J
Santa Fe Springs, CA 90670
Phone: 562-404-8466, Fax: 562-404-2757

14.3 Date Prepared:

Oct 18, 2007

4. Device Name:

Rescue Internal Dental Implant System

5. Device Classification:

Status: Class II Special Controls
Name: Endosseous Implant and Accessories
Regulation Number: 21 CFR 872.3640 and 21 CFR 872.3630

6. Purpose:

The purpose of this 510(k) is to include the components that are to be used with the internal method in joining the fixtures and prosthetics to the prior 510(k) submission for the Rescue Internal Implant System.

7. Device Description and Intended Use:

Rescue Internal Implant System consists of machined titanium, screw-form, root-form endosseous dental implants. It is 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 can be used where

smaller implants have failed.

8. Performance Standards:

FDA has not established a performance standard applicable to endosseous implants. The materials in the Rescue Internal Implant System meet applicable standards.

9. Device Description:

Rescue Internal Implant System is an integrated system of endosseous dental implants which designed to support prosthetic devices for partially or fully edentulous patients. Rescue Internal Implant Fixture Systems consist of two-stage, root-form dental implants, associated with abutment systems, and the instruments.

10. Facking / Labeling / Product Information:

Rescue Internal Implant System follows the guidance of the 21 CFR 872.3640 and 21 CFR 872.3630.

11. Substantial Equivalence Comparison:

Rescue Internal Implant System is essentially an addition to the predicate device previously cleared for marketing by FDA, Rescue Internal Implant System (K063216). The noted difference in the design and material does not effectively change the performance of the device. Rescue Internal Implant System is substantially equivalent to marketed BIOCON Dental Implants (K010185 and K050712).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 11 2008

MegaGen Company, Limited
C/O Dr. Steve Chang
U.S. Agent / Consultant
KoDent Incorporated
13340 E. Firestone Boulevard, Suite J
Santa Fe Springs, California 90670

Re: K073058
Trade/Device Name: Rescue Internal Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: March 11, 2008
Received: March 14, 2008

Dear Dr. 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.

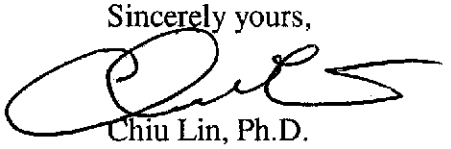
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-3150 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

K073058

Indication for Use

510(K) Number (if known):

Device Name: Rescue Internal Implant System

Indications For Use:

The Rescue Internal Implant System is intended to be surgically placed in the maxillary or mandibular molar areas for the purpose 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.

Robert S Betz DDS for Dr. Susan Runner

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

510(k) Number: K073058

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

(Part 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

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

Concurrence of CDRH, Office of Device Evaluation (ODE)