U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

FDA

Certificate of 510(k)
Awarded to

Megagen Co., Ltd.
114-8, Eupchun-Ri, Jain-Myun, Gyeongsan, Gyeongbuk, South Korea

510(k) Premarket Notification Number:
K073058

This is to certify that Rescue Internal Implant System has been evaluated for product safety and efficacy by the U.S. FDA and cleared for marketing in the United States of America.

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 endentulous individuals. These implants are indented to be used where smaller implants have failed.
Product Class:	Implant, Endosseous, Root-Form
Product Code:	DZE
Trade Name:	**Rescue Internal Implant System**
Regulation Number:	21 CFR 872.3640
Regulatory Class:	Class II
FDA Approval Date:	April 11, 2008

Presented by: Official Correspondent, Consultant and U.S. FDA Designated Agent

KoDent

Kodent Inc.
13340 E. Firestone Blvd. Suite J, Santa Fe Springs, CA 90670 USA

Dr. Steve Chang

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 Butz 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)