K053353

APR 19 2006

13. 510(K) SUMMARY

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

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

13-9. Device Description

13-1. 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
13-2. US Agent / Contact Person	Dae Kyu Chang 13340 E. Firestone Blvd. Suite J Santa Fe Springs, CA 90670 Phone : 562-404-8466, Fax : 562-404-2757
13-3. Date Prepared	November 30, 2005
13-4. Device Name	RESCUE® IMPLANT SYSTEMS
13-5. Classification Name	Endosseous Dental Implant System
13-6. Device Classification	Class II Dental Devices panel 21 CFR ξ 872.3640 Regulation Number: 872.3640
13-7. Predicate Devices	BICON Implant Systems (K01085, K050712)
13-8. Performance	Laboratory testing was conducted to determine device functionality and conformance to design input requirements.

Rescue® Implant System is an integrated system of endosseous dental implants which designed to support prosthetic devices for partially or fully edentulous patients. Rescue® implant Fixture Systems consist of two-stage, root-form dental implants, associated with abutment systems, which provide the clinician with screw and cement retained restoration for multi-mount, screw retained restoration for octa abutment, and cement retained restoration for solid abutment restorative options. The devices covered by this submission are Rescue® Implant Fixtures, Retained Restoration Abutment System.

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13-10. 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®. Rescue ™ Implant Systems (Rescue ™ Implant Fixtures, Rescue Protective Cap, and Rescue Implant System Surgery Tray) will be packaged.

13-11. Intended Use

The Rescue® 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.

13-12. Substantial Equivalence Comparison

13-13. Comparative Data

Comparison between the Rescue® Implant System, and BICON Implant

Characteristic	Rescue Dental Implant Systems	BICON Dental Implant System K010185, K050712
Manufacturer	MegaGen Co., Ltd.	BICON Dental Implants
Indications for Use	Mandible and Maxilla Endosseous Dental Implant & Accessories	Mandible and Maxilla Endosseous Dental Implant & Accessories
Design:	External Hex and Morse Taper	External Hex and Morse Taper
Endosseous Implant Material	C.P Titanium and It's Alloy	C.P Titanium and It's Alloy
Implant Sterile	Yes	Same
Sterilization Method	Gamma	Gamma
Implant Diameters	6.0, 6.5, 7.0,8.0	4.5, 6.0
Implant Lengths	7.0 – 10.0 mm	5.7-6.0mm
Attachments	Various abutments and components	Equivalent
Product Code	DZE & NHA	Same

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 0 2006

Mega'Gen Company, Limited
C/O Mr. Dae Chang
Kodent, Incorporated
13340 E. Firestone Boulevard, Suite J
Santa Fe Springs, California 90670

Re: K053353
Trade/Device Name: Rescue Dental Implant System
Regulation Number: 872.3640
Regulation Name: Endosseous dental implant
Regulatory Class: II
Product Code: DZE
Dated: March 30, 2006
Received: April 3, 2006

Dear Mr. 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.

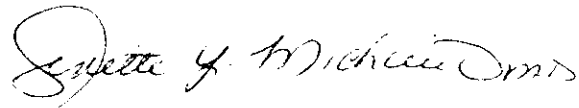
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 594-4618. 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/dsma/dsmamain.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

K053353

Indication for Use

510(K) Number (if known): K053353

Device Name: Rescue Dental Implant System

Indications for Use:

The Rescue® 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.

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)

Division of General Hos...
...Devices

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