K070562

13. 510(K) SUMMARY

MAY 18 2007

Mega'Gen Co., Ltd.
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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

13-1. 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	May 1, 2007
13-4. Device Name	EZ PLUS ® 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	EXFEEL IMPLANT SYSTEM(K052369)
13-8. Performance	Laboratory testing was conducted to determine device functionality and conformance to design input requirements.

13-9. Device Description

The EZ Plus Implant system consists of machined titanium, screw-form, root-form endosseous dental implant. The system is used as two stage, root-form dental implants, associated with abutment systems, which provide the clinician with the screw (for UCLA abutments) and cement (for solid abutments) retained restoration for multi-mount options. Fixtures, the prosthetics, and the surgical instruments are produced and packaged separately. All included devices in the system are covered by this submission.

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®. EZ PLUS™ Implant Systems (EZ Plus™ Implant Fixtures, EZ Plus Protective Cap and EZ Plus Implant system surgery tray) will be packed.

13-11. Intended Use

The EZ Plus Implant Systems are intended to be surgically placed in the upper or lower jaw to support prosthetic devices, such as artificial teeth, and to restore a patient's chewing function. This may be accomplished using either a two stage surgical procedure or a single stage surgical procedure. Large angle abutments (e.g. 25°) on small diameter implants of the EZ Plus internal connection system are intended for the anterior region of the mouth and not intended for use in the posterior region of the mouth due to limited strength of the implant.

13-12. Substantial Equivalence Comparison

13-12-1. Comparative data

Content	Subject Device	Precedent Device
510(K) Number	Not available yet	K052369
Characteristic	EZ Plus Implant System	ExFeel Implant System
Manufacturer	MegaGen Co., Ltd.	MegaGen Co., Ltd.
Indications for Use	Mandible and Maxilla Endosseous Dental Implant & Accessories	Mandible and Maxilla Endosseous Dental Implant & Accessories
Design:	Internal and External Hex	Internal and External Hex
Endosseous Implant Material	Commercial pure titanium	Commercial pure titanium
Implant Sterile	Yes	Yes
Sterilization Method	Gamma	Gamma
Implant Diameters	- Internal Type Implant: 3.3,4.0, 5.0mm - External Type Implant 3.3, 4.0, 5.0mm	3.5, 4.1, 4.8mm(Internal) 3.30, 3.75, 4.0, 5.0mm(External)
Implant Lengths	-Internal Type Implant : 8.0, 10.0,11.0, 13.0,15.0, 18.0mm - External Type Implant : 8.0,10.0, 11.0, 13.0, 15.0, 18.0mm	- Internal Type Implant: 7.0, 8.5, 10.0, 11.5, 3.0mm - External Type Implant: 8.5, 10.0, 11.5, 13.0, 15.0, 18.0mm
Attachments	Various abutments and components	Various abutments and components
Product Code	DZE	DZE

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 18 2007

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

Re: K070562
Trade/Device Name: EZ Plus Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: NHA
Dated: May 1, 2007
Received: May 4, 2007

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 (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,

Janette Y. Michaud MD.

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

Indication for Use

510(K) Number (if known): _____

Device Name: EZ Plus Implant System

Indications For Use:

The EZ Plus Implant Systems are intended to be surgically placed in the upper or lower jaw to support prosthetic devices, such as artificial teeth, and to restore a patient's chewing function. This may be accomplished using either a two stage surgical procedure or a single stage surgical procedure. Large angle abutments (e.g. 25°) on small diameter implants of the EZ Plus internal connection system are intended for the anterior region of the mouth and not intended for use in the posterior region of the mouth due to limited strength of the implant.

Prescription Use ✓ 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 Runge

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Number K070562