K053354

APR 13 2006

12. 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

13-1. 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	Intermezzo ™ Plus
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	Intermezzo Implant Systems (K051018)
13-8. Performance	Laboratory testing was conducted to determine device functionality and conformance to design input requirements.

13-9. Device Description

Intermezzo ™ Plus Implant System is an integrated system of endosseous dental implants which are intended for use in partially or fully edentulous mandibles and maxillae in support of overdentures.

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®. Intermezzo ™ Plus will be packed.

13-11. Intended Use

Intermezzo ™ Plus are designed for use in dental implant surgery and are intended to be used in a manner in which the implants integrate with the bone (osseointegration). The system is intended for use in partially or fully edentulous mandibles and maxillae, in support of overdentures.

13-12. Substantial Equivalence Comparison

Intermezzo ™ Plus (Intermezzo ™ Fixtures) and predicate implant systems share a substantially equivalent intended use. Intermezzo ™ Plus (Intermezzo ™ Implant Systems K051018) are similar in fundamental scientific technology in that they are all threaded, root form implants constructed of titanium. Any differences between the two devices do not raise new questions of safety and effectiveness. The subject and predicate devices are similar in size and materials. When compared with the predicate devices, no new questions of safety or effectiveness have been raised for the Intermezzo ™ Plus Fixture.

13-13. Comparative Data

Comparison between the Intermezzo ™ Plus and Intermezzo ™ Implant System,

Characteristic	Intermezzo ™ Plus	Intermezzo ™ Implant Systems (K051018)
Manufacturer	MegaGen Co., Ltd.	MegaGen Co., Ltd.
Indications for Use	Mandible and Maxilla Endosseous Dental Implant Fixture	Mandible and Maxilla Endosseous Dental Implant & Accessories
Endosseous Implant Material	C.P Titanium Gr.3	C.P Titanium Gr.3
Implant Sterile	Yes	Yes
Sterilization Method	Gamma	Gamma
Implant Diameters	2.5 – 3.1 mm	1.6 – 3.1 mm
Implant Lengths	10.0 – 15.0 mm	10.0 – 15.0 mm
Product Code	DZE	DZE

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 13 2006

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

Re: K053354
Trade/Device Name: Intermezzo Plus Fixture
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 (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

K053354

Indication for Use

510(K) Number (if known): K053354

Device Name: Intermezzo Plus Fixture

Indications for Use:

Intermezzo ™ Plus are designed for use in dental implant surgery and are intended to be used in a manner in which the implants integrate with the bone (osseointegration). The system is intended for use in partially or fully edentulous mandibles and maxillae, in support of overdentures.

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)

Robert S Beck DDS for Dr Susan Runner

...ay, General Hospi...

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