10. 510(K) SUMMARY SEP 2 2005 K051018

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Gyeongsan, Gyeongbuk
South Korea
Phone : 82-53-857-5770
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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

10-1. 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
10-2. US Agent / Contact Person	Dae Kyu Chang 13340 E. Firestone Blvd. Suites J Santa Fe Springs, CA 90670 Phone : 562-404-8466, Fax : 562-404-2757
10-3. Date Prepared	April 14, 2005
10-4. Device Name	INTERMEZZO™ IMPLANT SYSTEMS Intermezzo ™ Fixtures, Intermezzo ™ Protective Cap, and Intermezzo ™ Surgery Tray
10-5. Classification Name	Endosseous Dental Implant System
10-6. Device Classification	Class II Dental Devices panel 21 CFR ξ 872.3640 Regulation Number: 872.3640
10-7. Predicate Devices	IMTEC Sendax / MDI (Mini Dental Implant System) & Nobel Biocare / IPI (Immediate Provisional Implant System)
10-8. Performance	Laboratory testing was conducted to determine device functionality and conformance to design input requirements.

10-9. Device Description

Intermezzo ™ Implant System is an integrated system of endosseous dental implants which designed to support prosthetic devices for partially or fully edentulous patients. Intermezzo ™ Implant System consists of Intermezzo ™ Implant Fixtures, Intermezzo Cap, and Implant System Surgery Tray. Implant Fixture Systems consist of one-stage, root-form dental implants, associated with protective cap, which provide the clinician to maintain the patients' gingival contour. The system also includes surgical and restorative instrumentation: lance drills, twist drills, unification drills, and handpiece drivers and hand drivers to provide the clinician to choose only those components required for each clinical situation. The devices covered by this submission are Intermezzo ™ Implant Fixtures, Intermezzo Protective Cap, and Intermezzo Implant System Surgery Tray.

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

10-11. Intended Use

Intermezzo ™ Implant Systems is threaded one-piece implants designed for orthodontic one-stage surgical procedures in upper and lower jaw to provide a means of prosthetic attachment to restore a patient's chewing function. Intermezzo ™ Implant System consists of single-stage, root-form dental implants. The system is designed to provide immediate provisional implant to provide temporary support for prosthetic devices during the healing phase of permanent root form implants. Depends on a patient's quality of bone condition, Intermezzo ™ Fixtures are to be removed within six to ten weeks after the surgery. The system is intended for immediate placement in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cement retained, screw retained, or overdenture restorations.

10-12. Substantial Equivalence Comparison

Intermezzo ™ Implant Systems (Intermezzo ™ Implant Fixtures, Intermezzo ™ Protective Cap, and Intermezzo ™ Surgery Tools) and predicate implant systems share a substantially equivalent intended use. IMTEC Sendax / MDI (Mini Dental Implant System), Nobel Biocare / IPI (Immediate Provisional Implant System) and Intermezzo ™ Implant Systems (Intermezzo ™ Implant Fixtures, Intermezzo ™ Protective Cap, and Intermezzo ™ Surgery Tools) are similar in fundamental scientific technology in that they are all threaded, root form implants constructed of titanium with sandblasted surfaces. The subject and predicate devices are similar in size and materials. All three systems offer associated accessories and instruments. When compared with the predicate devices, no new questions of safety or effectiveness have been raised for the Intermezzo ™ Implant system.

10-13. Conclusion

The data submitted in this 510(K) Notification is to legally sale the following devices in U.S. market:

- Intermezzo Fixtures (Sizes: 1.6mm, 2.0mm, 2.5mm, 3.1mm)
- Intermezzo Protective Cap
- Surgical Tools – Drill (Lance Drill, Twist Drill, and Unification Drill)
  – Driver (Handpiece Connector, and Hand Driver)

The Intermezzo ™ Implant Systems (Intermezzo ™ Implant Fixtures, Intermezzo ™ Protective Cap, and Intermezzo ™ Surgery Tools) are substantially equivalent to the products such as IMTEC Sendax / MDI (Mini Dental Implant System) and Nobel Biocare / IPI (Immediate Provisional Implant System).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 2 2005

MegaGen Company Limited
C/O Mr. Dae Kyu Chang
KoDent, Incorporated
13340 East Firestone Boulevard, Suites J
Santa Fe Springs, California 90670

Re: K051018
Trade/Device Name: Intermezzo Implant Systems
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: July 29, 2005
Received: August 1, 2005

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.

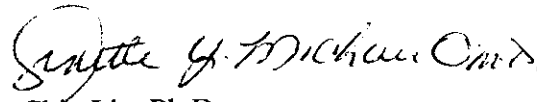
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

Indications for Use

510(k) Number (if known): K051018

Device Name: INTERMEZZO ™ IMPLANT SYSTEMS

Indication For Use:

The Intermezzo ™ Implant Systems are intended to load immediately in partially or fully edentulous mandibles and maxillae to serve as temporary support for provisional prosthetic device during the healing phase of permanent endosseous dental implants.

Prescription Use___x___ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

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

510(k) Number K051018