K101890

FEB - 3 2011

510(K) PREMARKET NOTIFICATION SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

1. Submitter:

Hyun Jung Kim

MegaGen Implant Co., Ltd.
377-2 Kyochon-Ri, Jain-Myun
Gyeongsan, Gyeongbuk, South Korea

Phone: 82-53-857-5770

Fax : 82-53-857-5432

2. US Agent/Contact:

Joyce Bang

Kodent Inc.

325 N. Puente st. Unit B. Brea, CA 92821

Phone: 714525-0114, Fax: 714-525-0116

3. Date Prepared: June 14, 2010

4. Device Name: Ball Abutment System

5. Device Classification:

Status: Class II

Name: Endosseous Implant Abutment

Regulation Number: 21 CFR 872.3630

Product Code: NHA

6. Purpose:

The purpose of this 510(k) is to include the components that are to be used with the internal external method in joining the fixtures and prosthetics to the prior 510(k) submission for the Ball Abutment System.

7. Device Description:

The abutments with the following diameters are available in sizes of 2.85mm, 3.50mm, 4.10mm, 5.00mm, and 6.00mm. The male part for each diameter is available in gingival heights of 2.0mm, 4.0mm, and 6.0mm, and the ball head diameter is 2.25mm. There are a total of 15 different size ball abutment systems being offered by Megagen.

External type

The lower part of the Ball Abutment is composed of internal hex or internal circle so that the external hex of fixture can be inserted. It can combine with screw to be fixed. The top part of the abutment is ball type, and the ball head diameter is 2.25mm, and it is designed to be able to connect with Dalbo Plus which is fixed on overdenture.

Internal type

This type of abutment is inserted and combined with fixture in order to support the overdenture. The sides of lower part of the abutment have been constructed with an 11° so that they can contact with upper part of the inner fixture. The top part of the abutment is designed as a ball type, and the ball head diameter is 2.25mm. This type of design enables to be connected with Dalbo Plus, overdenture.

8. Indication for use

The Ball Abutment Systems are used for implant retained mucosa-supported restorations, such as overdentures where the patient is fully edentulous in the arch to be restored. There are two types of Ball Abutment system, internal and external type, and the ball abutment technique is used on Ball Abutment System implants in the maxille or mandible.

9. Performance Standards:

FDA has not established a performance standard applicable to ball abutment system. The materials in the Ball Abutment Systems meet applicable standards.

10. Materials:

These devices are manufactured from Ti-6Al-4V ELI and stainless steel per ASTM and ISO standards.

11. Packing / Labeling / Product Information:

Ball Abutment System follows the guidance of the 21 CFR 872.3630.

12. Substantial Equivalence Comparison

Ball Abutment System is substantially equivalent to Osstem Implant Co., Ltd, Altatec GmbH (K063861, K051636). Testing and other comparisons have established that the subject of Ball Abutment System is substantially equivalent in design, materials, indications and intended use, packaging, labeling, and performance to other predicate devices of the type currently marketed in the U.S. This device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device, and it can be demonstrated that the device is as safe and effective as the predicate device, and that the new device does not raise different questions regarding safety and effectiveness as compared to the predicate device. It has been shown in this 510(k) submission that the differences between the Ball Abutment System and the predicate devices do not raise any questions regarding its safety and effectiveness. The Ball Abutment system, as designed and manufactured, is as safe and effective as the predicate devices and therefore is determined to be substantially equivalent to the referenced predicate devices.

13. Review:

The Ball Abutment has the same device characteristics as the predicate device. Its materials, dimensions, and intended use are similar to devices currently marketed worldwide.

The Ball Abutment has been subjected to extensive safety, performance, and product validations prior to release. Safety tests have been performed to ensure the devices comply to applicable industry and US regulations.

14. Conclusions:

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification Osstem Implant Co., Ltd, Altatec GmbH concludes that the ball abutment is safe and effective and substantially equivalent to predicate devices as described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Megagen Company, Limited
C/O Ms. Joyce Bang
Kodent
325 N. Puente Street, Unit B
Brea, California 92821

FEB - 3 2011

Re: K101890
Trade/Device Name: Ball Abutment System
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: December 22, 2010
Received: January 26, 2011

Dear Ms. Bang:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Anthony D. Watson, B.S., M.S., M.B.A.
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): K101890

Device Name: Ball Abutment System

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Prescription Use X **AND/OR** **OverThe-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 Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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