MAR 2 1 2014

# 510(k) Summary

(K132144)

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

Date: 02/21/2014

1. **Applicant / Submitter**

KJ Meditech Co., Ltd.
959-21 Daechon-dong, Buk-gu, Gwang-ju, 500-470, South Korea
Tel: +82-62-972-5476
Fax: +82-62-973-2809

2. **Submission Contact Person**

LK Consulting Group USA, Inc.
1515 E Katella Ave. Unit 2115, Anaheim, CA 92805
Priscilla Juhee Chung
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Email: juhee.c@lkconsultinggroup.com

3. **Device**

Trade Name: Kerator
Common Name: Dental Implant System
Classification Name: Endosseous Dental Implant System
Product Code: DZE, NHA
Classification regulation: 21CFR872.3640

2. **Predicate Device:**

Hero & IS Dental Implant System by KJ Meditech Co., Ltd. (K121047)
Kerator by KJ Meditech Co., Ltd. (K112787)
Locator Implant Anchor by Zest Anchors Inc. (K994257)

3. **Description:**

The Kerator is a dental implant system made of Titanium 6AL 4V ELI alloy intended to be surgically placed in the bone of the upper or lower jaw arches for loading after a conventional healing period. There are one fixture model and three abutment models in the Kerator. Among three abutment models, one model is compatible with

the Kerator fixture, and the other two abutment models are compatible with the fixtures made by other manufacturers. The implant may be used to replace one or more missing teeth. The system is similar to other commercially available products based on the intended use, the technology used, the claims, the material composition employed and performance characteristics. The surface of the fixture has been treated with R.B.M (Resorbable Blast Media) and the head part of the abutment has TiN coating over it. The Kerator abutment is placed into the dental implant to provide support for a prosthetic restoration.

▪ Kerator implant fixtrue

- Implant Type: Bone Level Implant
- Connection Type: Internal Hexagon
- Body Design: Tapered design enables placement near impringing anatomical structures while maximizing
- Size: 4.75mm Dia. x 10mm L

▪ Kerator abutments

1) AO Type:
- Connection type: This abutment is used with the Kerator fixture(Internal H exagon).
- Size Range: 3.87mm Dia. x 8.55 ~ 14.55mm L.

2) AR Type:
- Connection type: This abutment is used with the Megagen AnyRidge Fixture (5.0mm Dia., Internal Hexagon)
- Size Range: 3.87mm Dia. x 7.0~13.5mm L.

3) AT Type:
- Connection type: This abutment is used with the Astra Tech Fixture (3.0mm and 4.0mm Dia., Internal Hexagon)
- Size Range: 3.87mm Dia. x 8.5~13.7mm L.

**4. Indication for use:**

The Kerator fixture is intended for use in partially or fully edentulous mandibles and maxillae, in support of multiple-unit restorations. The Kerator abutments are intended use with overdentures or partial dentures. Kerator AO type is compatible with Kerator fixture and the following types are compatible with the fixtures made by other manufacturers as indicated below.

| Kerator Abutment Type | Fixture Trade Name | Manufacturer | Model Name | Size(Diameter) |
|---|---|---|---|---|
| AR401 | ANYRIDGE INTERNAL IMPLANT SYSTEM | Megagen | FANIHX5010 | 5.0Ø |
| AT301 | ASTRA TECH IMPLANT SYSTEM | ASTRA TECH AB | 24983 | 3.0 Ø |
| AT401 | ASTRA TECH IMPLANT SYSTEM | ASTRA TECH AB | 24940 | 4.0 Ø |

## 5. Basis for Substantial Equivalence

The design features and sizing of the components were compared between the subject device and the predicate devices and the Kerator found to be substantially the same as these systems. It is manufactured from the same FDA recognized materials and is indicated for the same intended uses as these systems. There are no significant differences between the Kerator and other systems currently being marketed which would adversely affect the use of the product. It is substantially equivalent to other devices in design, function, material and intended use.

## 6. Non-Clinical Testing

- Sterilization validating testing has been performed in accordance with ISO 11737-1 & ISO 11737-2 for gamma sterilization and ISO 17665-1 and ISO 17665-2 for steam sterilization.
- The three year of shelf life has been validated through accelerating testing.
- Chemical and SEM image analyses have been performed to verify that there is no residual after RBM treatment on the fixtures.

## 7. Conclusion

The subject devices and the predicate devices have the same intended use and have the same technological characteristics. The subject and predicate implants are all made of commercially pure titanium and have the same surface treatments.

Overall, the Kerator has the following similarities to the predicate devices:
* has the same intended use,
* uses the same operating principle,
* incorporates the same basic design,
* incorporates the same material and the surface treatment.

Based on the similarities, we conclude that the Kerator is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

March 21, 2014

KJ Meditech Company, Limited
C/O Ms. Priscilla Juhee Chung
Regulatory Affairs Consultant
LK Consulting Group USA, Incorporated
1515 E Katella Avenue, Unit 2115
Anaheim, CA 92805

Re: K132144
Trade/Device Name: Kerator
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: February 10, 2014
Received: February 14, 2014

Dear Ms. Chung:

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 contact 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. 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,

Erin I. Keith -S

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
*See PRA Statement on last page.*

510(k) Number *(if known)*
K132144

Device Name
Kerator

Indications for Use *(Describe)*
The Kerator fixture is intended for use in partially or fully edentulous mandibles and maxillae, in support of multiple-unit restorations. The Kerator abutments are intended use with overdentures or partial dentures. Kerator AO type is compatible with Kerator fixture and the following types are compatible with the fixtures made by other manufacturers as indicated below.

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Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Mary S. Runner -S
2014.03.20
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