AUG 8 2012

510(k) Summary
(K112787)

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

Date: 08/06/2012

1. Submitter

	Submitter
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2. U.S Agent/Contact Person

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Priscilla Chung
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3. Device

Trade Name: Kerator
Common Name: Abutment for Endosseous Implant
Classification Name: Endosseous dental implant abutment
Product Code: NHA
Classification regulation: 21CFR872.3630

4. Predicate Device:

Locator Implant Anchor by Zest Anchors, Inc. (K994257)
Branemark System 3.3mm Fixture by NOBELPHARMA USA, INC.(K944683)
Branemark System 4.00 mm Fixture by NOBELPHARMA USA, INC.(K925764)
Branemark System 5.0 X 14mm Fixture by NOBELPHARMA USA, INC.(K925761)
Astratech Implant System by ASTRA TECH AB (K091239)
Replace Tiunite Endosseous Implant by NOBEL BIOCARE UAS INC (K023113)
4.5.* 6.0mm Dental Implant and 6.0*6.0 mm Dental Implant by BICON, INC.(K050712)
Bicon Dental Implant System 3.0mm Bicon Dental Implant (K101849)

K112787

Paragon Implant System by CORE-VENT BIO-ENGINEERING, INC. (K953101)
ITI Dental Implant System by INSTITUT STRAUMANN AG (K033984)

5. Description:

The devices covered in this submission are abutments which are placed into the dental implant to provide support for a prosthetic restoration. The Kerator is made from Titanium grade Ti-6Al-4V ELI (meets ASTM Standard F-136) and compatible with several fixtures made by other manufactures.

6. Indication for use:

The Kerator is appropriate for use with overdentures or partial dentures retained in whole or in part by endosseous implants in the mandible or maxilla.

The Kerator is compatible with the following fixtures.

Kerator Model No.	Fixture Description	Manufacturer
B331 - B337	Branemark 3.3 Type	NOBELPHARMA USA, INC.
B401 - B407	Branemark 4.0 Type	
B501 - B507	Branemark 5.0 Type	
AS351 - AS357	Astra3.5 Type	ASTRA TECH AB
AS401 - AS407	Astra 4.0 Type	
G400 - G406		
SRS350 - SRS356	Replace 3.5 Type	Nobel Biocare USA, Inc.
SRS450 - SRS457	Replace 4.3 Type	
SRS500 - SRS506	Replace 5.0 Type	
BC201 - BC207	Bicon 2.0(well) Type	BICON, INC.
BC301 - BC307	Bicon 3.0(well) Type	
PA350 - PA356	Paragon 3.5 Type	CORE-VENT BIO-ENGINEERING, INC.
PA450 - PA456	Paragon 4.5 Type	
T401 - T407	ITI 4.0 Type	INSTITUT STRAUMANN AG

7. Basis for Substantial Equivalence

The Kerator is substantially equivalent to previously marketed device, Locator Implant Anchor (K994257) manufactured by Zest Anchors Inc. The design features and sizing of the components were also compared 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 these other devices in design, function, material and intended use.

Item	Subject Device	Predicate Device
510(K) Number	N / A	K994257
Device Name	Kerator	Locator Implant Anchor
Manufacturer	KJ Meditech Co., Ltd.	Zest Anchors Inc.
Product Code	NHA	NHA
Indications for Use	The Kerator is appropriate for use with overdentures or partial dentures retained in whole or in part by endosseous implants in the mandible or maxilla	The Locator Implant Anchor abutment for endosseous dental implants is appropriate for use with overdentures or partial dentures retained in whole or in part by endosseous implants in the mandible or maxilla
Performance Characteristics	The Kerator is an abutment which is placed into dental implant to provide support for a prosthetic restoration.	The Locator Implant Anchor is an abutment which is placed into dental implant to provide support for a prosthetic restoration.
Material (Abutment)	Titanium 6Al 4V ELI alloy ASTM F136	Titanium 6Al 4V ELI alloy ASTM F136
Material (Male Socket)	DuPont Zytel 101L NC-10 Nylon Low Density Polyethelene 993	DuPont Zytel 101L NC-10 Nylon Low Density Polyethelene 993
Surface Treatment	TiN coating only for the head part of the abutment.	TiN coating only for the head part of the abutment
Recommended Sterilization Method	Autoclave	Autoclave

8. Non-Clinical Testing

- The Kerator is compatible with several fixtures made by other manufactures. In order to claim the compatibility with those fixtures, the reverse engineering analysis was conducted to verify if Kertor has the same sizes and the tolerance as the predicate device which is already being marketed as the compatible ones for them. According to the test results, we conclude that they have the same size and tolerance as well as the design.
- The retention test has been carried out to confirm the ability of the abutments to resist pullout from the male cap / male housing assemblies.

9. Conclusion

Based on the information provided in this premarket notification, KJ Meditech Co., Ltd. concludes that Kerator is substantially equivalent to the predicate device 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

KJ MEDITECH Company, Limited
C/O Ms. Priscilla Chung
LK Consulting Group
951 Starbuck Street, Unit J
Fullerton, California 92833

AUG 8 2012

Re: K112787
Trade/Device Name: Kerator
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: July 26, 2012
Received: July 31, 2012

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 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

Indications for Use

510(k) Number (if known): K112787

Device Name: Kerator

Indications For Use:

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Prescription Use __√__ **AND** **Over-The Counter Use**_____
(Per 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)

Susan Runner

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

510(k) Number: K112787