K131117

JUL 2 6 2013

510(k) Summary

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

Date: ___05/22/2013___

1. Submitter:

Name: Contact:	KUWOTECH Co., Ltd. 50 Cheomdan venture so-ro, 37 beon-gil, Buk-gu, Gwang-ju, Republic of Korea Tel: +82-62-971-0182 Fax: +82-62-971-0185

2. Submission Correspondent:

Priscilla Chung
LK Consulting Group USA, Inc.
1515 E. Katella Ave. Unit 2115,
Anaheim, CA 92805
Phone: 714-202-5789 Fax: 714-409-3357
Email: juhee.c@lkconsultinggroup.com

3. Device:

Proprietary Name:	Zirmon Series
Common Name:	Dental Frame Material for Dental Prosthesis
Classification Name:	Porcelain Powder for Clinical Use
Classification:	Class II, 21 CFR 872.6660
Classification Product Code:	EIH

4. Predicate Device:

Vita In-Ceram YZ® Cubes for Cerec® (K022996) by VITA Zahnfabrik GmbH & Co. KG

5. Device Description:

The Zirmon Series is zirconia-based ceram provided in shapes of square and circle used to manufacture cores of all ceramic crowns, and is classified into ISO6872 Type 2 Class 1. This dental porcelain for cutting process is provided by shaping and semi-sintering zirconia powder and is used to manufacture ceramic restoration with cutting process by

dental MAD/MAM, computer-assisted design system, or manufacturing units, CAD/CAM system.

6. Intended Use:

The Zirmon Series is indicated for use as a substructure for porcelain fused ceramic fixed dental restorations; namely crown, bridges, inlays, and onlays.

7. Performance Data(Non-Clinical):

The following properties were tested based on the referenced standards. All the test results met the preset test criteria.

- ISO 6872 - Package, Uniformity, Freedom from extraneous materials, Radioactivity, Chemical solubility, Flexural strength, and Linear Thermal Expansion Coefficient
- ISO 13356 - Monoclinic Phase Rate and Flexural strength
- ISO 10993-5 - Cytotoxicity
- ISO 10993-11 - Acute systemic toxicity
- ISO 10993-10 - Oral Mucosa Irritation & Sensitization
- Other bench testing – Appearance, dimension and weight spec test

8. Substantial Equivalence

The Zirmon Series is substantially equivalent to the Vita In-Ceram YZ® Cubes for Cerec® (K022996). They share the same material and similar physical / chemical properties. The main difference is the dimensions and the subject device offers more shapes; however, the differences do not raise new safety or performance issues. The performance testing results presented in the 510K supports that the Zirmon Series is substantially equivalent in safety and effectiveness to the predicate device.

9. Conclusion:

Based on the testing results, KUWOTECH Co, Ltd concludes that the Zirmon Series is substantially equivalent in safety and effectiveness 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

July 26, 2013

KUWOTECH Co., Ltd.
C/O Ms. Priscilla Chung
Official Correspondent
LK Consulting Group USA, Inc.
1515 East Katella Avenue, Unit 2115
Anaheim, CA 92805

Re: K131117
Trade/Device Name: Zirmon Series
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: II
Product Code: EIH
Dated: May 23, 2013
Received: May 28, 2013

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,

Mary S. Runner -S

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

Enclosure

Indications for Use

510(k) Number (if known): K131117

Device Name: Zirmon Series

Indications for Use:

The Zirmon Series is indicated for use as a substructure for porcelain fused ceramic fixed dental restorations; namely crown, bridges, inlays, and onlays.

Prescription Use __√__		**Over-The Counter Use**_____
(Per 21 CFR 801 Subpart D)	**AND**	**(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)

Sheena A. Green -S
2013.07.30 11:51:56 -04'00'

for M. Susan Runner, DDS, MA

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

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