October 11, 2019

U&C International Co., Ltd.
% Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group USA, Inc.
1150 Roosevelt, STE 200
Irvine, California 92620

Re: K191902
Trade/Device Name: Razor, Everest, U&C Liquid
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain powder for clinical use
Regulatory Class: Class II
Product Code: EIH
Dated: July 10, 2019
Received: July 16, 2019

Dear Priscilla 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Srinivas Nandkumar, Ph.D.
Acting Director
DHT1B: Division of Dental Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K191902

Device Name
Razor, Everest, U&C Liquid

Indications for Use *(Describe)*

The Razor and Everest are indicated for use by dental technicians in the construction of custom made all ceramic restorations for anterior and posterior location.

U&C Liquid can be used as an accessory to zirconium dioxide dental restorative material to provide individual tooth (or teeth) shading. It is intended to be used solely by certified dental technicians for fabrication of zirconium dioxide restorations for individual dental patients.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary
K191902

This summary of 510(K) is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: July 10, 2019

1. Applicant / Submitter

U&C International Co., Ltd.
RM 1F/2F, 13, Digital-ro 27-gil,
Guro-gu, Seoul, Republic of Korea
Tel: +82-02-865-7714

2. Submission Correspondent

Priscilla Chung
LK Consulting Group USA, Inc.
1150 Roosevelt, STE 200
Irvine CA 92620
Tel: 714.202.5789 Fax: 714.409.3357
Email: juhee.c@LKconsultingGroup.com

3. Device

- Trade Name: Razor, Everest, U&C Liquid
- Common Name:
  Dental Frame Material for Dental Prosthesis
  Liquid Stain for Dental Zirconium Prosthesis
- Classification Name: Porcelain Powder for Clinical Use
- Product Code: EIH
- Classification regulation: Class II, 21 CFR 872.6660

4. Predicate Device

BruxZir™ Anterior (K143330) by Prismatik Dentalcraft, Inc.
LUMINESSE® PRE-SINTERED ZIRCONIA COLORING LIQUID (K143090) by Talladium, Inc.

5. Description:

Razor and Everest are zirconia-based ceramic provided in various shapes such as round and square, and they are used to manufacture cores of all ceramic crowns, and are classified into ISO 6872 Type 2 Class 5.
They are used to manufacture ceramic restorations through cutting process by dental MAD/MAM, computer-assisted design system, or CAD/CAM system. The subject device offers 31 different shades A0, A1, A2, A3, A4, B1, B2, B3, B4, C1, C2, C3, C4, D2, D3, D4, ML A1, ML A2, ML A3, ML A4, ML B1, ML B2, ML B3, ML B4, ML C1, ML C2, ML C3, ML C4, ML D2, ML D3, ML D4 to meet the needs of different patients' tooth colors. It also offers various shape types to be used with various jigs for CAD/CAM milling machine.

U&C Liquid is water-based solution. It is used for the individual staining of dental zirconia frameworks and restorations prior to the final sintering. It enables trained dental technicians to adjust the restoration to match the natural color of the patient's teeth. The liquid has 25 shades. 25 shades are available in 30ml, 50ml and 100ml volumes.

6. Indication for use:

The Razor and Everest are indicated for use by dental technicians in the construction of custom made all ceramic restorations for anterior and posterior location.

U&C Liquid can be used as an accessory to zirconium dioxide dental restorative material to provide individual tooth (or teeth) shading. It is intended to be used solely by certified dental technicians for fabrication of zirconium dioxide restorations for individual dental patients.

7. Basis for Substantial Equivalence

7.1. Razor™ and Everest

The subject device is substantially equivalent to the predicate device, BruxZir™ Anterior (K143330) made by Prismatik Dentalcraft, Inc. Both the device has the same indications for Use, materials, and technological characteristics. The composition rate might be different between the devices, however, the subject device meets the requirements of ISO 6872 and 10993, therefore, these difference does not raise a question in substantial equivalence.

	Subject Device	**Predicate Deice**
510(k) Number	-	K143330
Device Name	Razor, Everest	BruxZir™ Anterior
Common Name	Porcelain, Powder for clinical use	Porcelain, Powder for clinical use
510k Applicant	U&C International	Prismatik Dentalcraft, Inc.

Indication For Use	The Razor and Everest are indicated for use by dental technicians in the construction of custom made all ceramic restorations for anterior and posterior location.	The device is indicated for use by dental technicians in the construction of custom made all ceramic restorations for anterior and posterior location.
CTE(coefficient of thermal expansion)	$(10.3\pm0.5)\times10^{-6}K^{-1}$ (meeting the ISO 6872 requirement)	$11\times10^{-6}K^{-1}$ (meeting the ISO 6872 requirement)
Flexural strength	>500MPa (meeting the ISO 6872 requirement)	>650MPa (meeting the ISO 6872 requirement)
Chemical solubility	<2000 μg/㎠ (meeting the ISO 6872 requirement)	<2000 μg/㎠ (meeting the ISO 6872 requirement)
Material Component	ZrO_2, HfO_2, Y_2O_3, Al_2O_3, SiO_2, Fe_2O_3, Er_2O_3	ZrO_2, HfO_2, Y_2O_3, Al_2O_3, SiO_2, Fe_2O_3, Er_2O_3
Shade	31 shades	5 shades
Principle of Operation	Install the block on milling machine, upload a designed file and process it	Install the block on milling machine, upload a designed file and process it
Biocompatibility	Non-toxic and biocompatible (Meeting the ISO 10993-3, 5,10 and10993-11 requirements)	Non-toxic and biocompatible (Meeting the ISO 10993-3, 5,10 and10993-11 requirements)

7.2. U&C Liquid

The subject device is substantially equivalent to the predicate device, LUMINESSE® PRE-SINTERED ZIRCONIA COLORING LIQUID (K143090) made by Talladium, Inc. Both the device has the same indications for Use and technological characteristics. They even have similar or the same pH, boiling point, density and specific gravity range. Both devices are soluble in water. The raw material composition rate might be different between the devices, however, the subject device meets the requirements ISO 10993, therefore, this difference would not raise a question in substantial equivalence.

	Subject device	**Predicate device**
Device Name	U&C Liquid	LUMINESSE® PRE-SINTERED ZIRCONIA COLORING LIQUID
510(k)		K143090
Product Code	EIH	EIH
Manufacturer	U&C International	Talladium, Inc.
Technology	Water-based with inorganic pigments	Water-based with inorganic pigments
Indication for Use	U&C Liquid can be used as an accessory to zirconium dioxide dental restorative material to provide individual tooth (or teeth) shading. It is intended to be used solely by certified dental technicians for fabrication of zirconium dioxide restorations for individual dental patients.	Luminesse Pre-Sintered Zirconia Coloring Liquid is a device that can be used as an accessory to zirconium dioxide dental restorative material such as Luminesse ZR blanks to provide individualized tooth (or teeth) shading. It is intended to be used solely by certified dental technicians for fabrication of all ceramic

		restorations for individual dental patients.
Principles of Operation	Brush or immerse zirconia ceramic with coloring liquid before sintering	Brush or immerse zirconia ceramic with coloring liquid before sintering
Type of Packaging	Liquid container	Liquid container
Packaging Volume(ml)	30,50 and 100mL	100 and 250mL
Shade	25 colors	16 colors
Storage Conditions	1 year at room temperature	3-4 years at 4-10 °C
General Physical Form	Liquid	Liquid
Sterility	Non-Sterile	Non-Sterile
pH	6.5-7.2	6.5-7.2
Boiling Point	100°C	100°C
Density	1.05-1.10 g/cm^3	1.05-1.10 g/cm^3
Specific Gravity	1.05-1.10	1.05-1.10
Solubility in Water	100%	100%

8. Non-Clinical Testing

- Biocompatibility testing: Cytotoxicity test in accordance with ISO 10993-5, Irritation and Skin Sensitization test in accordance with ISO 10993-10, Subacute/Subchronic Toxicity in accordance with ISO 10993-11.
- Performance tests for the blocks in accordance with ISO 6872 and ISO 13356 including Radiation Emission, Flexural Strength, Flexural Strength after low thermal heating, Thermal Expansion Coefficient, Monoclinic Phase Rate, Other bench testing - Appearance, Dimensions, Packaging, Uniformity, Free from extraneous materials
- Performance tests for the liquid in accordance with ISO 6872, ISO 7491, ISO 6872, ISO 10271 including Appearance, Capacity, Packaging, Color Stability, and Extraction
- Shelf life test for U&C Liquid

The test results supported that the subject device is substantially equivalent to the predicate devices.

9. Conclusion

Based on the information and the test results in the submission, we conclude that the Razor, Everest, and U&C Liquid are substantially equivalent to the predicate devices.