April 5, 2021

Vatech Acucera, Inc.
Kyung Wook Kwon
Manager
2544, Nambuk-daero, Idong-eup, Cheoin-gu
Yongin-si, Gyeonggi-do 17138
Korea, South

Re: K203499
Trade/Device Name: Perfit ZR ST Dental Zirconia blank, Perfit ZR UT Dental Zirconia blank
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: December 30, 2020
Received: January 7, 2021

Dear Kyung Wook Kwon:

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,

Bobak Shirmohammadi -S

For Michael Adjodha
Assistant 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)*

K203499

Device Name
Perfit ZR ST Dental Zirconia blank, Perfit ZR UT Dental Zirconia blank

Indications for Use *(Describe)*

Perfit ZR ST Dental Zirconia blank and Perfit ZR UT Dental Zirconia blank are used for dental restorations using different CAD / CAM or manual milling machines. All blanks are processed through dental laboratories or by dental professionals.

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.

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510(k) Summary

The following 510(k) summary is being submitted as required by 21 CFR 807.92;

1. Submitter: Vatech acucera, Inc.

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Date Prepared: Mar. 31. 2021

510(k) number: K203499

2. Device Identification

Device Trade Name	Perfit ZR ST Dental Zirconia blank Perfit ZR UT Dental Zirconia blank
Common Name	Milling Block or Dental CAD/CAM Block
Classification Name, Number	Porcelain Powder for Clinical Use(21 CFR 872.6660)
Device Classification	II
Product Code	EIH

3. Predicated or legally marketed devices which are substantially equivalent

- Primary predicate: K141724, "Upcera Dental Zirconia Blank and Dental Zirconia Pre-Shaded Blank", manufactured by "Liaoning Upcera"

4. Device Description and Statement of Intended Use

The Perfit ZR ST Dental Zirconia blank and Perfit ZR UT Dental Zirconia blank consists of zirconium oxide which compresses ceramic for milling, grinding, and further firing. It is normally pre-sintered and milled by dental technician with CAD/CAM machine for shaping artificial teeth such as crowns, bridges, veneers, inlay etc.

The Perfit ZR ST Dental Zirconia blank and Perfit ZR UT Dental Zirconia blank are disc shaped zirconia oxide blanks made available in different versions and chemical compositions of various colors, shades and dimensions and will further process the discs by milling them to make final dental restorations such as crowns, bridges, veneers, inlays and on lays based on the anatomical rendering of the patient's teeth using CAD/CAM equipment. At the completion of the machining steps, the dental restoration is fired (i.e., sintered) in the oven to harden the ZrO2 so that its final properties can be achieved.

They are available in different models that differ in various specification and color. There are white zirconia products(W) and colored zirconia products, and colored zirconia is also divided into Monolayer(A1, A2, A3.5, A4, B1, B2, B3, B4, C1, C2, C3, C4, D2, D3, D4) color products , Shade multi-layer(A1 SM, A2 SM, A3 SM, A3.5 SM, A4 SM, B1 SM, B2 SM, B3 SM, B4 SM, C1 SM, C2 SM, C3 SM, C4 SM, D2 SM, D3 SM, D4 SM) color products and Trans&Shade multi-layer(A1 TM, A2 TM, A3 TM, A3.5 TM, A4 TM, B1 TM, B2 TM, B3 TM, B4 TM, C1 TM, C2 TM, C3 TM, C4 TM, D2 TM, D3 TM, D4 TM) color products.

The white zirconia is composed of ZrO2+HfO2+Y2O3 and an additional inorganic pigment: Al2O3 and Other oxide. The color zirconia products are derived from the same zirconia powder as the regular white zirconia powder, with the addition of very small amount of inorganic pigments: Fe2O3 +Pr2O3 +Er2O3. The inorganic pigments generate the color on the prosthetic dental device, after sintering at dental labs, that matches natural color of patient's teeth.

The composition of the Dental Zirconia Blocks including the white zirconia and the color zirconia conforms to ISO 13356:2015, Implants for surgery -Ceramic materials based on yttria-stabilized tetragonal zirconia (Y-TZP) and the performance conforms to ISO 6872:2015/Amd1:2018, Dentistry: Ceramic Materials.

5. Statement of Intended Use

Perfit ZR ST Dental Zirconia blank and Perfit ZR UT Dental Zirconia blank are used for dental restorations using different CAD / CAM or manual milling machines. All blanks are processed through dental laboratories or by dental professionals.

6. Non-clinical Test Conclusion

The results of comparative study performed according to ISO 6872:2015 were indicated
The performance of formed zirconia dental blanks meets the applicable requirements of the following FDA recognized standards:

- *ISO 6872: 2015- Dentistry-Ceramic Materials*
- *ISO 13356: 2015, Implant for surgery – Ceramic materials based on yttria-stabilized tetragonal zirconia (Y-TZP)*
- *ISO 10993-1:2018, Biological evaluation of medical devices — Part 5: Evaluation and testing within a risk management process*
- *ISO 10993-3: 2014 Biological evaluation of medical devices Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity.*
- *ISO 10993-5: 2009, Biological evaluation of medical devices - Part 5: Tests for In Vitro cytotoxicity.*
- *ISO 10993-6 Biological evaluation of the medical devices – Part 6: Tests for Local Effects after Implantation.*
- *ISO 10993-10: 2010, Biological evaluation of medical devices - Part 10: Tests for irritation('Oral mucosa irritation) and skin sensitization.*
- *ISO 10993-11:2017 Biological evaluation of medical device – Part 11: Tests for systemic toxicity*

Physical and mechanical properties of the subject device were evaluated according to ISO 6872:2015 and ISO 13356: 2015.
According to ISO 6872:2015, the subject device is classified into the following:

Type II: All other forms of ceramic products.
Class 4: Monolithic ceramic for prostheses involving partially or fully covered substructure for four or more units or fully covered substructure for prostheses involving four or mor

units.

Bench testing was performed per ISO 6872:2015 and ISO 13356:2015 to ensure that the "Perfit ZR ST Dental Zirconia blank" and "Perfit ZR UT Dental Zirconia blank" met it specifications. All tests were verified to meet acceptance criteria.

A series of tests were conducted on the subject device for the Biocompatibility

Biological endpoint	Reference	Test result and SE
Cytotoxicity	ISO 10993-05	No cytotoxic reactivity under the condition of the study
Sensitization	ISO 10993-10	Not a sensitizer under the conditions of the study
Intracutaneous reactivity	ISO 10993-10	No intracutaneous reactivity
Systemic toxicity(acute)	ISO 10993-11	No systemic toxicity under the condition of the study
Genotoxicity	ISO 10993-03	No possibility of genotoxicity under the condition of the study

Bench test results allowed to conclude that Perfit ZR ST & Perfit ZR UT Dental Zirconia blank is substantially equivalent to the predicate devices for its intended use.

7. Clinical Test Conclusion
Clinical testing was not required for this submission.

8. Technical Characteristics and Substantial Equivalence
The following table shows similarities and differences of use, design, and material between our device and the predicate devices.

Table 1. General Device Characteristics Comparison Table

No.	Item	Subject Device	Predicate Device
1	Device Name	**Perfit ZR ST & Perfit ZR UT** Dental Zirconia blank	Upcera Dental Zirconia Blank and Dental Zirconia Pre-Shaded Blank
2	Manufacturer	Vatech acucera, Inc.	Liaoning Upcera
3	510(k) Number	K203499	K141724
4	Product Code	EIH	EIH
5	Class	II	II
7	Review Panel	Dental	Dental
8	Indications for Use	The Perfit ZR ST & Perfit ZR UT Dental Zirconia blank are used for dental restorations using different CAD / CAM or manual milling machines. All blanks are processed through dental laboratories or by dental professionals.	Upcera Dental Zirconia Blank and Dental Zirconia Pre-Shaded Blank are used for dental restorations using different CAD / CAM or manual milling machines. All blanks are processed through dental laboratories or by dental professionals.
9	Form	Block, disc form	Block, dis and rod form
10	Dimensions	Various	Various
11	Material	Regular: Zirconia (ZrO_2 + Y_2O_3 + HfO_2 + Al_2O_3 ≥ 99.0%) Pre-Shaded: Zirconia (ZrO_2 + Y_2O_3 + HfO_2 +	Regular: Zirconia (ZrO_2 + Y_2O_3 + HfO_2 + Al_2O_3 ≥ 99.0%) Pre-Shaded: Zirconia (ZrO_2 + Y_2O_3 + HfO_2 +

		Al2O3 ≥98.0%) Inorganic pigments (Fe2O3, Pr2O3, and Er2O3 < 2.0%)	Al2O3 ≥98.0%) Inorganic pigments (Fe2O3, Pr2O3, and Er2O3 < 2.0%)
12	Color	None, and Pre-shaded (for pre-shaded series) and two different aesthetic effects (single and multilayer)	None, and Pre-shaded (for pre-shaded series).
13	Processing	Sintering at temperature > 1500 °C	Sintering at temperature > 1500 °C
14	Conditions of Use	Professional use for the fabrication of artificial teeth in fixed or removable dentures, of jacket crowns, facings, and veneers.	Professional use for the fabrication of artificial teeth in fixed or removable dentures, of jacket crowns, facings, and veneers.
15	Single Use	Yes	Yes
16	Supplied Sterile	No	No
17	Packaging	Single blank(disk) per box	Single blank(disk) per box
18	Biocompatibility Testing	Tested to ISO 10993-1	Tested to ISO 10993-1
19	Performance Testing	Tested to ISO 6872	Tested to ISO 6872

Our device is essentially identical to the predicate device in terms of indications for use, design, material, and processing between our device and the predicate devices. We have some minor differences are compared with the predicate device. One is that the predicate device includes rod form more than ours. Shape excluding rod form can be considered the same as our product. Another one is that our device including not only single layer color product but also including multilayer color product to satisfy the aesthetic needs. The different colors are originated from the different constituent of color additive (such as Fe_2O_3, Er_2O_3, and the different aesthetic effects are originated from the different padding method used in the process of dry pressing, they are very small amount(< 2.0%).These differences do not raise any concerns in the subject device, and this is demonstrated by biocompatibility testing.

7. Conclusion

The information discussed above demonstrates that Perfit ZR ST & Perfit ZR UT Dental Zirconia blank, as effective, and performs as well as or better than the predicate devices

8. Declarations

This summary includes only information that is also covered in the body of the 510(k).
This summary does not contain any puffery or unsubstantiated labeling claims