June 24, 2021

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

Re: K203590
Trade/Device Name: Perfit FS Dental Zirconia Fully Sintered Block
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: May 26, 2021
Received: May 26, 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,

For Michael E. Adjodha, M.ChE.
Assistant Director
DHT1B: Division of Dental and ENT 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)*
K203590

Device Name
Perfit FS Dental Zirconia Fully Sintered Block

Indications for Use *(Describe)*

The Perfit FS Dental Zirconia Fully Sintered Block is used for dental restorations using different CAD / CAM or manual milling machines. All blocks 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.

510(k) Summary
K203590

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

1. Submitter: Vatech acucera, Inc.

Address: 2544, Nambuk-daero, Idong-eup, Cheoin-gu, Yongin-si, Gyeonggi-do, Korea (17138)

Phone No. +82-31-8005-1851

Fax No. +82-31-8005-1888

Contact Person: 1) Kwon, Kyung Wook

Phone: +82-31-8005-1851

E-mail: kyungwook.kwon@vatechmcis.com

2) Hwang, Haesun

Phone: +82-10-3824-6922

E-mail: Sunny.hwang@medi-guide.com

Date Prepared: June 23. 2021

2. Device Identification

510(k) Submission	K203590
Device Trade Name	Perfit FS Dental Zirconia Fully Sintered Block
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

- Predicated device: K141724, "Upcera Dental Zirconia Blank and Dental Zirconia Pre-Shaded Blank", manufactured by "Liaoning Upcera"
- Reference device: K203499, "Perfit ZR ST Dental Zirconia Blank, Perfit ZR UT Dental Zirconia Blank", manufactured by "Vatech acucera, Inc.".

4. Device Description

The Perfit FS Dental Zirconia Fully Sintered Block consists of zirconium oxide which compresses ceramic for milling, grinding. It is a preshaded, fully sintered product and milled by dental technician with CAD/CAM machine for shaping artificial teeth such as crowns, bridges, veneers, inlay etc.

The Perfit FS Dental Zirconia Fully Sintered Block are zirconia oxide block 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.

They are available in different models that differ in various specification and color. There are white zirconia products(White) 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(ML A1/A2/A3, A1M, A2M, A3M, A3.5M, A4M)color products.

The white zirconia is composed of ZrO2+Y2O3+Nb2O5 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 and other oxide.

The composition of the Dental Zirconia Block 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 Indications for Use

The Perfit FS Dental Zirconia Fully Sintered Block is used for dental restorations using different CAD / CAM or manual milling machines. All blocks 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 testing conducted on the subject formed zirconia dental blanks met 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: Partially or fully covered substructure for three-unit prostheses involving molar

restoration.
Bench test results allowed to conclude that Perfit FS Dental Zirconia Fully Sintered Block 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	Reference Device	Remark
1	Device Name	Perfit FS Dental Zirconia Fully Sintered Block	Upcera Dental Zirconia Blank and Dental Zirconia Pre-Shaded Blank	Perfit ZR ST Dental Zirconia Blank, Perfit ZR UT Dental Zirconia Blank	
2	Manufacturer	Vatech acucera, Inc.	Liaoning Upcera	Vatech acucera, Inc.	
3	510(k) Number	K203590	K141724	K203499	
4	Product Code	EIH	EIH	EIH	Identical
5	Class	II	II	II	Identical
7	Review Panel	Dental	Dental	Dental	Identical
8	Indications for Use	The Perfit FS Dental Zirconia Fully Sintered Block is used for dental restorations using different CAD / CAM or manual milling machines. All blocks 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.	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.	Identical
9	Form	Block form	Block, disc, and rod form	Block, disc form	Identical
10	Dimension	Various	Various	Various	Identical
11	Material	Regular: Zirconia (ZrO_2 + Y_2O_3 +Nb_2O_5 Al_2O_3 ≥	Regular: Zirconia (ZrO_2 + Y_2O_3 + HfO_2 + Al_2O_3 ≥	Zirconia (ZrO_2 + Y_2O_3 + HfO_2 + Al_2O_3 ≥ 99.0%) Pre-Shaded:	Different 1

		99.0%) Pre-Shaded: Zirconia (ZrO_2 + Y_2O_3 + Nb_2O_5 + Al_2O_3 ≥99.0%) Inorganic pigments (Fe_2O_3, MnO_2, and Er_2O_3 < 1.0%)	99.0%) Pre-Shaded: Zirconia (ZrO_2 + Y_2O_3 + HfO_2 + Al_2O_3 ≥98.0%) Inorganic pigments (Fe_2O_3, Pr_2O_3, and Er_2O_3 < 2.0%)	Zirconia (ZrO_2 + Y_2O_3 + HfO_2 + Al_2O_3 ≥98.0%) Inorganic pigments (Fe_2O_3, Pr_2O_3, and Er_2O_3 < 2.0%)	
12	Color	None, and Pre-shaded (for preshaded series)	None, and Pre-shaded (for preshaded series).	None, and Pre-shaded (for preshaded series).	Identical
13	Flexural strength	≥500 MPa	- - -	≥ 500 MPa	Identical
14	Solubility	<2000μg/cm²	- - -	<2000μg/cm²	Identical
15	Radioactive	uranium-238 active concentration ≤ 1.0 Bq/g.	- - -	uranium-238 active concentration ≤ 1.0 Bq/g.	Identical
16	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.	Professional use for the fabrication of artificial teeth in fixed or removable dentures, of jacket crowns, facings, and veneers.	Identical
17	Single Use	Yes	Yes	Yes	Identical
18	Supplied Sterile	No	No	No	Identical
19	Packaging	3 ea blocks per box	Single blank(disk) per box	Single blank(disk) per box; 4 ea blocks per box	Different 2
20	Biocompatibility Testing	Tested to ISO 10993-1	Tested to ISO 10993-1	Tested to ISO 10993-1	Identical
21	Performance Testing	Tested to ISO 6872	Tested to ISO 6872	Tested to ISO 6872, Class 4	Identical

Our device is equivalent to the predicate device in terms of indications for use, design, material, and processing. There are some minor differences as compared to the predicate device. One is that the predicate device is available in rod, block or disc form vs the subject device is only available in block form. Shape excluding rod form can be considered the same as the subject device. Another difference is the subject device includes not only single layer color product but also multilayer color product. The

different colors are derived from the different constituents of color additive (such as Fe_2O_3, Er_2O_3, MnO_2), and the different aesthetic effects are derived from the different padding method used in the process of dry pressing. They are present in very small amounts(< 1.0%).
Also, the subject device contains Nb_2O_5.
Both the subject and predicate device have similar physical/mechanical and biocompatibility properties that met the requirements of ISO 6872 (Class 4) and ISO 10993.

7.	**Conclusion**	The information discussed above demonstrates that Perfit FS Dental Zirconia Fully Sintered Block is substantially equivalent to the identified predicate device.