January 7, 2022

Aidite (Qinhuangdao) Technology Co., Ltd.
Boyle Wang
Official Correspondent
Shanghai Truthful Information Technology Co., Ltd.
RM.1801,No.161,East Lu Jiazui Rd.,Pudong
Shanghai, Shanghai 200120
CHINA

Re: K213570
Trade/Device Name: Dental Zirconia Ceramic
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: November 8, 2021
Received: November 10, 2021

Dear Boyle Wang:

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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K213570

Device Name
Dental Zirconia Ceramic

Indications for Use *(Describe)*

Dental Zirconia Ceramic are used for dental restorations using different CAD/CAM or manual milling machines. All blanks are processed thought 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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K213570

510(k) Summary

This summary is submitted in accordance with 21 CFR 807.92.

1.0 Submission Sponsor

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Designated Submission Correspondent

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Date of Preparation: Oct.8,2021

2.0 Device Information

Trade name: Dental Zirconia Ceramic
Common name: Powder, Porcelain
Classification name: Porcelain powder for clinical use
Production code: EIH
Regulation number: 21 CFR 872.6660
Classification: Class II
Panel: Dental

3.0 Identification of Predicate Device and Reference Device

Predicate Device:

510(k) Number: K141724
Product Name: Upcera Dental Zirconia Blank & Dental Zirconia Pre-Shaded Blank
Manufacturer: Liaoning Upcera Company Limited.

Reference Device:

510(k) Number: K210884
Product Name: 1Derful HS, 1Derful HT
Manufacturer: 1DERFUL, INC.

4.0 Indication for Use Statement

Dental Zirconia Ceramic are used for dental restorations using different CAD/CAM or manual milling machines. All blanks are processed thought dental laboratories or by dental professionals.

5.0 Device Description

The subject device, Dental Zirconia Ceramic, are derived from dental porcelain powder that has been processed into their final net shapes. These blanks are then being further fabricated (using hot press or CAD/CAM technologies) into all ceramic restorations such as veneers, inlay/ onlay, partial crowns,anterior crowns, posterior crowns. The ceramics material is composed of ZrO_2, Y_2O_3, Al_2O_3 and other oxides. It also contains inorganic pigments to provide different shades on the product surface，totally 16 colors(A1,A2,A3,A3.5,A4,B1,B2,B3,B4,C1,C2,C3,C4,D2,D3,and D4), with the addition of very small amount ($<0.5\%$) of inorganic pigments: Fe_2O_3 $+Er_2O_3+Co_3O_4$.

The composition of the Dental Zirconia Ceramic 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.

The Dental Zirconia Ceramic is provided as non-sterile.

6.0 Summary of Non-Clinical Testing

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

ISO 6872:2015/Amd1:2018 Dentistry - Ceramic Materials

Items	Acceptance Criteria	Test Method	Test Result
Uniformity	The inorganic pigment(s) used to produce the colour of a fired dental ceramic shall be uniformly dispersed throughout the dental ceramic material.	Visual inspection	Product uniformity is qualified. Pass

<table>
<tr><td>Freedom from extraneous materials</td><td>Dental ceramic materials shall be free from extraneous materials.</td><td>Visual inspection</td><td>No extraneous materials.
Pass</td></tr>
<tr><td>Radioactivity</td><td>Dental ceramic materials shall not have an activity concentration of more than 1.0Bqg^{-1} of ^{238}U</td><td>ISO 6872:2015/Amd1:2018</td><td>There was no activity detected.
Pass</td></tr>
<tr><td>Flexural strength</td><td>The flexural strength of the product should not be less than 900MPa.</td><td>ISO 6872:2015/Amd1:2018</td><td>Average 943.1 MPa
Pass</td></tr>
<tr><td>Linear thermal expansion coefficient</td><td>The linear thermal expansion coefficient should be (10.5±0.5) ×10^{-6} K^{-1}.</td><td>ISO 6872:2015/Amd1:2018</td><td>Average 10.47 × 10^{-6}
Pass</td></tr>
<tr><td>Chemical solubility</td><td>The chemical solubility of the product should not be more than 2000 ug.cm^{-2}.</td><td>ISO 6872:2015/Amd1:2018</td><td>Average 13.5
Pass</td></tr>
<tr><td>Product composition(%)</td><td colspan="2"><table><tr><td>Item</td><td colspan="2">Requirements</td></tr><tr><td rowspan="4">Product composition(%)</td><td>ZrO_2</td><td>94％-95％</td></tr><tr><td>Y_2O_3</td><td>4.5％-5.5％</td></tr><tr><td>Al_2O_3</td><td>＜0.5％</td></tr><tr><td>Other oxide</td><td>＜0.5％</td></tr></table></td><td>ZrO_2：94.56%；
Y_2O_3：5.34%；
Al_2O_3：0.005％；
Other oxide：0.095%</td></tr>
</table>

Biocompatibility Testing:

Biocompatibility testing per following standards are performed to verify the equivalent safety of the materials that are used:

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 and skin sensitization.
ISO 10993-11:2017 Biological evaluation of medical device – Part 11: Tests for systemic toxicity

7.0 Summary of Clinical Test

Clinical testing was not required for this submission.

9.0 Technological Characteristics and Substantial Equivalence

The following table shows similarities and differences of use, design, and material between our device and the predicate devices.

Table1 General Device Characteristics Comparison Table

Item	Subject Device	Predicate device	Reference device	Remark
510(k) No.	Pending	K141724	K210884	
Product Name	Dental Zirconia Ceramic	Upcera Dental Zirconia Blank & Dental Zirconia Pre-Shaded Blank	1DERFUL™ HS & 1DERFUL™ HT Zirconia	--
Product Code	EIH	EIH	EIH	Same
Regulation No.	872.6660	872.6660	872.6660	Same
Class	II	II	II	Same
Intended Use	Dental Zirconia Ceramic are used for dental restorations using different CAD/CAM or manual milling machines. All blanks are processed thought dental laboratories or by dental professionals.	Upcera Dental Zirconia Blank & Dental Zirconia Pre-Shaded Blank are used for dental restorations using different CAD/CAM or manual milling machines.All blanks are processed thought dental laboratories or by dental professionals.	1DERFUL™ HS & 1DERFUL™ HT Zirconia blanks are indicated for use in prosthetic dentistry to create porcelain (ceramic) prostheses (dentures, crowns and bridges). 1DERFUL™ HS & 1DERFUL™ HT Zirconia blanks are intended to be milled and fully sintered by a Dental Professional or Dental Laboratory before use. Full contour monolithic crowns and bridges in	Same with the Predicate Device

			anterior and posterior regions. Substructure ceramic for prostheses involving four or more units can be created.	
Prescription Use	Yes	Yes	Yes	Same
Shapes	Blocks	Blocks, disc, and rod.	Disc	Same
Color	Colour	None,and pre-shaded	None,and pre-shaded	Analysis 1
Materials	Zirconia(ZrO_2: 94%～95%; Y_2O_3: 4.5%～5.5% Al_2O_3: ＜0.5%) Inorganic pigments: Fe_2O_3 +Co_3O_4 +Er_2O_3 <0.5	Regular: Zirconia(ZrO_2+HfO_2+Y_2O_3+ Al_2O_3≥99.0); Pre-Shaded: Zirconia(ZrO_2+HfO_2+Y_2O_3+ Al_2O_3≥98.0) Inorganic pigments: Fe_2O_3 +Pr_2O_3 +Er_2O_3 <2.0	ZrO2+HfO2 +Y2O3 > 99; HfO2: < 2 Y2O3: 5.2 Al2O3: ≤ 0.05 Inorganic pigments: Fe_2O_3 +ErO_3 +Co_3O_4 & Er_2O_3 < 0.3	Analysis 1
Dimension	Various	Various	Various	Same
Density (pre sintering)	≥2.80g / cm^3	2.8~3.2 g/cm^3	Not Publicly available	Analysis 2
Density (post sintering)	≥ 6.0g / cm^3	≥ 6.02 g / cm^3	6.08 g/cm^3	Same
Sintering Temperature	1530 ℃	>1500℃	Not Publicly available	Analysis 3

Flexural strength	> 900MPa	≥900 MPa	>1000 MPa	Same
Solubility	<100 μg.cm-^{2}	<100μg/ cm^2	5.257 μg/cm2	Same
Radioactive	uranium-238 active concentration ≤ 1.0 Bq / g.	The activity concentration of U-238is not more than 1.0 Bq / g.	<0.03	Same
Single Use	Yes	Yes	Yes	Same
Sterile	Non-sterile	Non-sterile	Non-sterile	Same
Performance Test	Including: Uniformity,Freedom from extraneous materials, Radioactivity, Flexural strength, Linear thermal expansion coefficient, Chemical solubility which comply with ISO 6872	Comply with ISO 6872	Comply with ISO 6872	Same
Biocompatibility	Comply with ISO 10993-1:2018, FDA Guidance, tests included cytotoxicity, oral mucosa irritation, skin sensitization, pyrogenicity, acute systemic toxicity, subacute toxicity, subchronic	Comply with ISO 10993-1, FDA Guidance	Comply with ISO 10993-1, FDA Guidance	Same

	systemic toxicity, implantation effect and genotoxicity etc.			

Analysis:

The subject device is highly similar to the predicate device in terms of indications for use, design, material and processing.

The subject device is different from the predicate device in the following:

1) The subject device is color zirconia blocks. The chemical compositions of color zirconia are same with the that of reference device's pre-shaded zirconia. The color is originated from inorganic pigments Fe_2O_3, Co_3O_4 and Er_2O_3, that are of very small amount (<0.5%). All chemical ingredients in the subject device have been used in the predicate device and the reference device. Accordingly, it was concluded that the subject device is substantially equivalent in biocompatibility to the predicate device and the reference device.
2) The pre sintering mainly affects the hardness of products which reflects the easy degree of material machining operations. The pre sintering density of the proposed device is a little different with the predicated device, but it has no obvious effect on the hardness, this difference does not affect substantial equivalence.
3) The sintering temperature is >1500℃ for the predicated device, while this information is a little different with the subject device which is about 1530℃. This difference does not affect substantial equivalence as the sintering temperature mainly affects the physical and mechanical property of the dental blocks. Both the subject device and the predicate device have similar physical/mechanical properties that met the requirements of ISO 6872.

In summary, the main components of the subject device and its predicate are substantially equivalent, and the slight differences does not affect the substantial equivalence of the subject device when compared to the predicate device.

10.0 Conclusion

The conclusions drawn from the comparison and analysis above demonstrate that the differences between the subject device and the predicate device are insignificant in terms of substantial equivalence. The proposed device is substantially equivalent to the predicate device.