December 6, 2022

Aidite (Qinhuangdao) Technology Co., Ltd.
℅ Grace Liu
Consultant
Shenzhen Joyantech Consulting Co., Ltd
1713A, 17th Floor, Block A, Zhongguan Times Square,
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Shenzhen, Guangdong 518000
CHINA

Re: K222626
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: August 31, 2022
Received: August 31, 2022

Dear Grace Liu:

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 -S

Michael E. Adjodha, M.ChE.
Assistant Director
DHT1B: Division of Dental and
ENT Devices
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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)*
K222626

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 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

K222626

1. Contact Details

1.1 Applicant information

Applicant Name	Aidite (Qinhuangdao) Technology Co., Ltd.
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Date Prepared	2022-08-25

1.2 Submission Correspondent

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2. Device Information

Trade name	Dental Zirconia Ceramic
Common name	Dental Zirconia Ceramics
Classification	II
Classification name	Porcelain powder for clinical use
Product code	EIH
Regulation No.	21 CFR 872.6660

3. Legally Marketed Predicate Device

Trade Name	PRETTAU®, ICE and Z-WHITE zirconia blanks (Primary Predicate)
510(k) Number	K183304
Product Code	EIH
Manufacturer	ZIRKONZAHN SRL

4. Device Description

Dental Zirconia Ceramic is pre-shaded zirconia, and it's composed of yttria-stabilized zirconia. It contains ZrO_2+HfO_2+Y_2O_3+Al_2O_3 and very small amount of additional inorganic pigments

(Fe_2O_3+Er_2O_3+Co_3O_4). The inorganic pigments generate the color on the restorations, after sintering at dental labs, that matches natural color of patient's teeth.

Dental Zirconia Ceramic has six models mainly according to the flexural strength (i.e. ≥600Mpa and ≥800Mpa) and the shade uniformity in the whole blank (i.e. monolayer and multilayer). Each model also has several available shade variations. And it also offers various shapes and dimensions suitable for different milling systems.

The proposed device is processed into the dental restorations such as crowns, bridges, veneers, inlays and onlays based on the anatomical rendering of the patient's teeth using CAD/CAM (computer aided design / computer aided manufacturing) method or manual milling method.

The proposed device is a single-use device, provided non-sterile, and its performance conforms to ISO 6872:2015 Dentistry: Ceramic Materials.

5. Intended Use/Indication for Use

Dental Zirconia Ceramic 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. Substantial Equivalence Comparison

Table 1 Substantial Equivalence Comparison

Comparison item	Proposed Device (K222626)	Predicate Device (K183304)	Comment
Manufacturer	Aidite (Qinhuangdao) Technology Co., Ltd.	ZIRKONZAHN SRL	None
Product Name	Dental Zirconia Ceramic	PRETTAU®, ICE and Z-WHITE zirconia blanks	None
Product Code	EIH	EIH	Same
Regulation Number	21 CFR § 872.6660	21 CFR § 872.6660	Same
Classification	Class II	Class II	Same
Prescription Use	Yes	Yes	Same
Indications for Use	Dental Zirconia Ceramic are used for dental restorations using different CAD/CAM or manual milling machines. All blanks are processed through dental laboratories or by dental professionals.	Prettau®, Prettau® 2, Prettau® 2 Coloured, Prettau® 2 Dispersive, ICE Translucent, ICE Premium, ICE Abutment, ICE Translucent Plus, ICE Translucent Plus Coloured, ICE Translucent Plus Dispersive and Z-White are intended for the manufacturing of metal-free partial and single crowns, full arch occlusally screwed bridges, inlays, onlays, and veneers, full contour restorations as well as reduced	Similar

		structures in combination with veneering ceramics. The products are categorized into class 5 according to ISO 6872. Prettau® 3, Prettau® 3 Coloured, Prettau® 3 Dispersive, Prettau® 4 Anterior®, Prettau® 4 Anterior® Coloured and Prettau® 4 Anterior® Dispersive are destined for the manufacturing of metal-free partial and single crowns, max. 3-unit bridges, inlays, onlays and veneers, full contour restorations as well as for reduced structures in combination with veneering ceramics and implant superstructures for 3-unit restorations in the anterior and posterior tooth region. The products have to be categorized as class 4 according to ISO 6872. The products have been developed for use with Colour Liquid, ICE Zirkon Ceramics, ICE Zirkon Stains and ICE Zirkon Stains 3D. Observe the relative instructions of use when using these products. The blocks are suitable for all milling units, which are able to process presintered zirconia and which have the proper clamping device for the corresponding block.	
Class (per ISO 6872:2015)	Class 4 Multilayer-3D, UTC, UTM Class 5 Multilayer-3D pro, SHTPC, SHTPM	Class 4 Prettau® 3, Prettau® 4 Anterior Class 5 Prettau®, Prettau® 2, ICE group, Z-White	Same
Composition	Based on yttria-stabilized zirconia	Based on yttria-stabilized zirconia	Similar
Color	Color	White, Color	Similar

Intended User	Professional dental technicians	Professional dental technicians	Same
Single Use	Yes	Yes	Same
Sterile	Non-sterile	Non-sterile	Same
Physical Properties	Conform to ISO 6872:2015	Conform to ISO 6872:2015	Same
Uniformity	Uniform	Uniform	Same
Freedom from extraneous materials	Free from extraneous materials	Free from extraneous materials	Same
Radioactivity	≤ 1.0 $Bq \cdot g^{-1}$	≤ 1.0 $Bq \cdot g^{-1}$	Same
Flexural strength	Multilayer-3D, UTC, UTM: ≥ 600 MPa Multilayer-3D pro, SHTPC, SHTPM: ≥ 800 MPa	Prettau® 3, Prettau® 4 Anterior: ≥ 600 MPa Prettau®, Prettau® 2, ICE group, Z-White: ≥ 900 MPa	Similar
Chemical solubility	< 100 $\mu g/cm^2$	< 100 $\mu g/cm^2$	Same
Linear thermal expansion coefficient	Multilayer-3D, Multilayer-3D pro, SHTPM: $(10.4\pm0.5)\times10^{-6}\,K^{-1}$ SHTPC: $(10.3\pm0.5)\times10^{-6}\,K^{-1}$ UTC: $(10.0\pm0.5)\times10^{-6}\,K^{-1}$ UTM: $(10.5\pm0.5)\times10^{-6}\,K^{-1}$	Not publicly available	Different
Biocompatibility	Conform to ISO 7405:2018	Conform to ISO 10993-1	Similar
Labeling	Complied with 21 CFR part 801	Complied with 21 CFR part 801	Same

The proposed device has the similar indication for use as the predicate device as well as comparable technical and biocompatibility properties and characteristics, and the minor differences don't raise any additional questions for safety and effectiveness, therefore, the proposed device is substantially equivalent to the predicate device.

7. Non-clinical Testing

- **Performance Testing**

The performance tests were performed according to *ISO 6872:2015 Dentistry - Ceramic materials*, and the test results showed that the proposed device meets the requirements specified in the standard (see Table 2).

Table 2 Summary of Performance Testing

Test Item	Test Results					
	Multilayer-3D	UTC	UTM	Multilayer-3D pro	SHTPC	SHTPM
Uniformity	Uniform	Uniform	Uniform	Uniform	Uniform	Uniform
Freedom from extraneous materials	Free from extraneous materials	Free from extraneous materials	Free from extraneous materials	Free from extraneous materials	Free from extraneous materials	Free from extraneous materials
Radioactivity ($Bq.g^{-1}$)	<0.019	<0.018	<0.019	<0.021	<0.020	<0.019
Flexural strength (Mpa)	Incisal end: 635.60 Middle part: 804.40 Root end: 931.30	840.69	725.34	985.15	950.95	1014.51
Linear thermal expansion coefficient ($\times 10^{-6} K^{-1}$)	Incisal end: 10.4 Middle part: 10.3 Root end: 10.3	10.1	10.5	10.5	10.3	10.4
Chemical solubility ($\mu g/cm^2$)	28	11	21	38	13	5
Shrinkage factor	1.233	1.244	1.237	1.234	1.241	1.250

- **Biocompatibility Testing**

  The biocompatibility tests were performed according to *ISO 7405:2018 Dentistry - Evaluation of biocompatibility of medical devices used in dentistry* (see Table 3), and the test results showed that the proposed device has no biocompatibility issues.

Table 3 Summary of Biocompatibility Testing

Biological Endpoint	Reference	Test Result
Cytotoxicity	ISO 10993-5:2009	No cytotoxicity under the conditions of the study
	ISO 7405:2018, 6.2	No cytotoxicity under the conditions of the study
	ISO 7405:2018, 6.3	No cytotoxicity under the conditions of the study
Skin Sensitization	ISO 10993-10:2010	No skin sensitization under the conditions of the study
Oral Mucosa Irritation	ISO 10993-10:2010	No oral mucosa irritation under the conditions of the study
Acute Systemic Toxicity	ISO 10993-11:2017	No acute systemic toxicity under the conditions of the study
Subchronic Systemic Toxicity	ISO 10993-11:2017	No subchronic systemic toxicity under the conditions of the study
Genotoxicity	ISO 10993-3:2014	No genotoxicity under the conditions of the study
Implantation	ISO 10993-6:2016	No local effects under the conditions of the study

The results of the non-clinical testing demonstrate that the proposed device is equivalent to the predicate device.

8. Clinical Testing

No clinical study is included in this submission.

9. Conclusions

The results of comparing the design specifications and non-clinical testing between the proposed device and the legally marketed predicate device (K183304) show that they are Substantially Equivalent (SE).