February 18, 2022

Shenzhen Yurucheng Dental Materials Co., Ltd.
℅ Grace Liu
Consultant
Shenzhen Joyantech Consulting Co. Ltd
1713A, 17th Floor, Block A, Zhongguan Times Square, Nanshan District
Shenzhen, Guangdong 518000
China

Re: K214005
Trade/Device Name: Zirconia Dental Ceramics
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: December 12, 2021
Received: December 21, 2021

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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K214005

Device Name
Zirconia Dental Ceramics

Indications for Use *(Describe)*
Zirconia Dental Ceramics are intended 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.

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

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510(k) Summary - K214005

1. Contact Details

1.1 Applicant information

Applicant Name	Shenzhen Yurucheng Dental Materials Co., Ltd.
Address	101-201, Building 4, No.1 Branch of Zhongcheng Life Science Park, No. 14 Zhongxing Road, Xiuxin Community, Kengzi Street Office, Pingshan District, Shenzhen, China
Contact person	Fiya Liao
Phone No.	+86-17727849963
E-mail	ppk-jidcvcvmr@dingtalk.com
Date Prepared	2022-02-17

1.2 Submission Correspondent

卓远天成	Shenzhen Joyantech Consulting Co., Ltd 1713A, 17th Floor, Block A, Zhongguan Times Square, Nanshan District, Shenzhen, Guangdong Province, China
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Contact person	Grace Liu; Field Fu;
Contact person's e-mail	grace@cefda.com; field@cefda.com
Website	http://www.cefda.com

2. Device Information

Trade name	Zirconia Dental Ceramics
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	Dental Zirconia Blocks
510(k) Number	K192262
Product Code	EIH
Manufacturer	De Corematrix Co.Ltd.

4. Legally Marketed Reference Device

Trade Name	X-cera Zirconia Blanks
510(k) Number	K153767
Product Code	EIH

Manufacturer	Shenzhen XiangTong Photoelectricity Technology Co., Ltd.

5. Device Description

Zirconia Dental Ceramics is composed of yttria-stabilized zirconia. It contains ZrO_2+HfO_2+Y_2O_3 and additional Al_2O_3 and other oxides. It offers various shapes and dimensions suitable for different milling systems. The performance of the proposed device conforms to *ISO 6872:2015 Dentistry: Ceramic Materials*.

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, and provided non-sterile.

6. Intended Use/Indication for Use

Zirconia Dental Ceramics are intended for dental restorations using different CAD/CAM or manual milling machines. All blocks are processed through dental laboratories or by dental professionals.

7. Substantial Equivalence Comparison

Table 1 Substantial Equivalence Comparison

Comparison item	Proposed Device (K214005)	Predicate Device (K192262)	Reference Device (K153767)	Comment
Manufacturer	Shenzhen Yurucheng Dental Materials Co., Ltd.	De Corematrix Co.Ltd.	Shenzhen XiangTong Photoelectricity Technology Co., Ltd.	None
Product Name	Zirconia Dental Ceramics	Dental Zirconia Blocks	X-cera Zirconia Blanks	None
Product Code	EIH	EIH	EIH	Same
Regulation Number	21 CFR § 872.6660	21 CFR § 872.6660	21 CFR § 872.6660	Same
Classification	Class II	Class II	Class II	Same
Prescription Use	Yes	Yes	Yes	Same
Indications for Use	Zirconia Dental Ceramics are intended for dental restorations using different CAD/CAM or manual milling machines. All blocks are processed through dental laboratories	Dental Zirconia Blocks are intended for use for the production of artificial teeth in fixed or removable dentures, or for jacket crowns, facing, and veneers. All Blocks are	X-cera Zirconia Blanks are indicated for the production of artificial teeth in fixed or removable dentures, or for jacket crowns, facings, and veneers.	Similar

	or by dental professionals.	processed through dental laboratories or by dental professionals.		
Class (per ISO 6872:2015)	Type II, Class 5	Type II, Class 5	Type II, Class 6 (per ISO 6872:2008)	Same
Intended User	Professional dental technicians	Professional dental technicians	Professional dental technicians	Same
Single Use	Yes	Yes	Yes	Same
Sterile	Non-sterile	Non-sterile	Non-sterile	Same
Shape	Cylinder, Cuboid, U-shape	Blocks, Disc	Cylinder, Disc, Block	Similar to reference device
Dimension	Various	Various	Various	Different
Color	White	White, Color	White	Similar
Composition	ZrO_2+HfO_2+Y_2O_3: ≥99% Y_2O_3: 4.5%~6.0% HfO_2: ≤5% Al_2O_3: ≤0.5% Other oxide: ≤0.5%	White ZrO_2+HfO_2+Y_2O_3: ≥99% Y_2O_3: 4.5%~6.0% HfO_2: ≤5% Al_2O_3: ≤0.5% Other oxide: ≤0.5%	ZrO_2: 88%~96% Y_2O_3: 4%~10% Al_2O_3: <1% HfO_2: <0.05% SiO_2: <0.5%	Same
Physical Properties	Conform to ISO 6872:2015	Conform to ISO 6872:2015	Conform to ISO 6872:2008	Same
Uniformity	Uniform	Uniform	Uniform	Same
Freedom from extraneous materials	Free from extraneous materials	Free from extraneous materials	Free from extraneous materials	Same
Radioactivity	≤ 1.0 $Bq·g^{-1}$	≤ 1.0 $Bq·g^{-1}$	≤ 1.0 $Bq·g^{-1}$	Same
Flexural strength	≥ 800 MPa	> 800 MPa	≥ 800 MPa	Similar
Chemical solubility	< 100 $\mu g/cm^2$	< 100 $\mu g/cm^2$	≤ 100 $\mu g/cm^2$	Same
Linear thermal expansion coefficient	$(10.5±0.5)×10^{-6}\,K^{-1}$	Not publicly available	$(10.5±0.5)×10^{-6}\,K^{-1}$	Different
Shrinkage factor	1.253±0.002	Not publicly available	Shrinkage: 19%~22%	Different
Fracture Toughness	≥ 5.0 $MPa*m^{1/2}$	≥ 5.0 $MPa*m^{1/2}$	≥ 5.0 $MPa*m^{1/2}$	Same

Biocompatibility	Conform to ISO 7405:2018, FDA Guidance	Conform to ISO 10993-1:2018, FDA Guidance	Conform to ISO 7405 and ISO 10993	Similar
Labeling	Complied with 21 CFR part 801	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.

8. 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	Judgment
Uniformity	Uniform	Pass
Freedom from extraneous materials	Free from extraneous materials	Pass
Radioactivity	<0.017 $Bq \cdot g^{-1}$	Pass
Flexural strength	1076.4 MPa	Pass
Linear thermal expansion coefficient	$10.7 \times 10^{-6} K^{-1}$	Pass
Chemical solubility	54.2 $\mu g/cm^2$	Pass
Shrinkage factor	1.254	Pass
Fracture Toughness	16.32 $MPa*m^{1/2}$	Pass

- **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

	6.2 of ISO 7405:2018	No cytotoxicity under the conditions of the study
	6.3 of ISO 7405:2018	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.

9. Clinical Testing

No clinical study is included in this submission.

10. Conclusions

The results of comparing the design specifications and non-clinical testing between the proposed device and the legally marketed predicate device (K192262) show that they are Substantially Equivalent (SE).