December 21, 2023

Shenzhen Yurucheng Dental Materials Co., Ltd.
℅ Shanfeng Jiang
Regulation Control Manager
Guangzhou Junyi Information Technology Co., Ltd.
Room 304, Building A, No. 62 Nanyun 2nd Road, Science Town
Huangpu District, Guangzhou City, Guangdong 510663
CHINA

Re: K233016
Trade/Device Name: Dental Glass Ceramics
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: September 22, 2023
Received: September 22, 2023

Dear Shanfeng Jiang:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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, MChE, RAC, CQIA
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)*

K233016

Device Name
Dental Glass Ceramics

Indications for Use *(Describe)*
Once finalized into a suitable design, the Dental Glass Ceramics are indicated for use as inlays, onlays, veneer, partial crowns and crowns.

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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Section 5 - 510(k) Summary

K233016

Date of Summary Preparation: September 22, 2023
Date of Modification: December 21, 2023

1. Submitter's Identifications

1. Submitter's Name: Shenzhen Yurucheng Dental Materials Co., Ltd.
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2. Correspondent's Identifications

2. Correspondent's Name: Guangzhou Junyi Information Technology Co., Ltd.
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3. Name of the Device

Device Classification Name: Powder, Porcelain
Regulation Description: Porcelain powder for clinical use
Trade Name: Dental Glass Ceramics
Model: HT, LT, ML-HT, ML-LT
Regulation Medical Specialty: Dental
Review Panel: Dental
Product Code: EIH
Regulation Number: 21 CFR 872.6660
Device Classification: Class II

4. The Predicate Devices

Predicate device: K202952 Amber Mill Q Series and Amber Mill Direct Series HASS CORP

5. Device Description

Dental Glass Ceramics is composed of SiO_2, Li_2O，K_2O,P_2O_5,Al_2O_3 and other oxides. The block is intended to be 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 block is a single-use device and provided non-sterile.

The performance of the dental blanks conforms to ISO 6872, *Dentistry — Ceramic materials*.

6. Intended Use of Device

Once finalized into a suitable design, the Dental Glass Ceramics are indicated for use as inlays, onlays, veneer, partial crowns and crowns.

7. Summary of Substantial Equivalence

Table 1 Comparison to Predicate Device

	Proposed Device	**Predicate device**	**Comparison**
510k Number		K202952	------
Product Code	EIH	EIH	Same
Classification Reg	21 CFR 872.6660	21 CFR 872.6660	Same
Proprietary Name	Dental Glass Ceramics	Amber Mill Q Series and Amber Mill Direct Series	------
Model:	HT, LT, ML-HT, ML-LT	------	------
Manufacturer	Shenzhen Yurucheng Dental Materials Co., Ltd.	HASS CORP	------
Indications for Use	Once finalized into a suitable design, the Dental Glass Ceramics are indicated for use as inlays, onlays, veneer, partial crowns and crowns.	Once finalized into a suitable design, the Amber Mill Q Series and Amber Mill Direct Series are indicated for use as inlays, onlays, veneer, partial crowns and	Same

		crowns.	
Materials	SiO_2, Li_2O , K_2O,P_2O_5,Al_2O_3 and other oxides	SiO_2, Li_2O, K_2O,P_2O_5,Al_2O_3 and other oxides	Same
Crystallization State as Supplied	Fully crystallized	Fully crystallized	Same
Device Design	Block	Block	Same
Various	Various Translucency : High translucency(HT) Low translucency(LT) Medium Opacity(MO)	Various Translucency : High translucency(HT) Low translucency(LT) Medium Opacity(MO)	Same
Shades	Shade : LT/ HT : 16 A-D and 4 Bleach MO : 5 MO0- MO4	Shade : LT/ HT : 16 A-D and 4 Bleach MO : 5 MO0- MO4	Same
Single Use	Yes	Yes	Same
Principle of Operation	Fabricating restorations using CAD/CAM system	Fabricating restorations using CAD/CAM system	Same
Sterile	Non-sterile	Non-sterile	Same
Type/Class per ISO 6872	Type Ⅱ, Class 3	Type Ⅱ, Class 3	Same
Flexural strength	> 300MPa (meeting the ISO6872 requirements)	> 300MPa (meeting the ISO6872 requirements)	Same
Chemical solubility	< 100 ug / cm2 (meeting the ISO6872 requirements)	< 100 ug / cm2 (meeting the ISO6872 requirements)	Same
Freedom from Extraneous Material	Shall be free from extraneous materials when assessed by visual inspection	Shall be free from extraneous materials when assessed by visual inspection	Same

	(meeting ISO 6872 requirements)	(meeting ISO 6872 requirements)	
Radioactivity	Activity concentration of uranium238 less than 1.0Bq g-1 (meeting the ISO6872 requirements)	Activity concentration of uranium238 less than 1.0Bq g-1 (meeting the ISO6872 requirements)	Same
Linear of thermal expansion	10.5 ± 0.5 × 10-6/℃ (meeting the ISO6872 requirements)	11.5 ± 0.5 × 10-6/℃ (meeting the ISO6872 requirements)	Same
Glass Transition Temperature	Tg:500 ± 20 ℃ (meeting ISO 6872 requirements)	Tg:500 ± 20 ℃ (meeting ISO 6872 requirements)	Same
Biocompatibility	Non-toxic and biocompatible (Meeting the ISO 10993-3, 5, 10，11 and 10993-6 Requirements)	Non-toxic and biocompatible (Meeting the ISO 10993-3, 5, 10，6 and 10993-11 Requirements)	Same
Discussion for Substantially Equivalent (SE)	The proposed device is essentially identical to the predicate devices in terms of indication for use, design between our device and the predicate devices.		

The proposed device is essentially identical to the predicate devices in terms of indication for use, design between our device and the predicate devices.

8. Summary of Non-Clinical Testing

Bench testing was performed per ISO 6872:2015 and internal procedures to ensure that the Dental Glass Ceramics met its specifications. All tests were verified to meet acceptance criteria. Test results on Product Code, Classification Reg, Indications for Use, Materials , Crystallization State as Supplied, Device Design , Shades , Single Use , Principle of Operation ,Sterile, Type/Class per ISO 6872, Flexural strength , Chemical solubility , Freedom from Extraneous Material , Radioactivity , Linear of thermal expansion , Biocompatibility and Glass Transition Temperature of the subject device are very similar to predicate device. Biocompatibility testing was performed to verify the equivalent safety of the materials that are used.

According to ISO 10993-1:2018, we evaluated and conducted the compatibility test for the proposed device. The following table shows the biocompatibility testing results.

Table 2 Biocompatibility testing

Item	Proposed device	Result
Cytotoxicity (ISO 10993-5:2009)	Under the conditions of this study, the test article was non cytotoxic for 2 h and was Mildly cytotoxic for 24 h in the filter diffusion method. Under the conditions of this study, the test article was Slight cytotoxic and was accepted in the agar diffusion method. Under the conditions of this study, the test article has no potential toxicity to L-929 cells.	Pass
Oral Mucosa Irritation (ISO 10993-10:2010)	The test article has no potential oral mucosa irritation in the Syrian hamsters.	Pass
Skin Sensitization Test (ISO 10993-10:2010)	The test article showed no evidence of causing delayed dermal contact sensitization in the guinea pig.	Pass
Subacute Systemic Toxicity Test (ISO 10993-11:2017)	There is no obvious histopathological difference in test group and control group. The structure of each organ in test group is normal, no abnormal histopathological changes in the table above was found.	Pass
Acute Systemic Toxicity (ISO 10993-11:2017)	The test article showed no evidence of causing acute system toxicity in the ICR mice.	Pass
In Vitro Mammalian Cell Gene Mutation Test (ISO 10993-3:2014)	Under the conditions of this study, the test article is considered non-mutagenic.	Pass
Bacterial Reverse Mutation Test (ISO 10993-3:2014)	Under the conditions of this study, the number of reverting colonies in the test article group is not equal to or greater than 2 times that of the spontaneous control, so the test article have no potential mutagenesis.	Pass
Muscle Implant 4 Weeks Test (ISO 10993-6:2016)	The test result showed that the test article did not induce local effects after implantation of biomaterials in rabbits under this condition.	Pass
Muscle Implant 13 Weeks Test (ISO 10993-6:2016)	The test result showed that the test article did not induce local effects after implantation of biomaterials in rabbits under this condition.	Pass

Note: Testing were Performed on Dental Glass Ceramics LT, with Pre-Shaded powder A4 (Due to the variety of Dental Glass Ceramics's models, LT-A4 with the most trace elements in type are selected as typical models for test) to cover the regular and Dental Glass Ceramics .

9. Clinical Test Conclusion

No clinical study is included in this submission.

10. Conclusion:

The conclusions drawn from the nonclinical tests demonstrate that subject device Dental Glass Ceramics performs as well as or better than the legally marketed predicate device K202952 Dental Glass Ceramics. Dental Glass Ceramics is substantial equivalent to the legally marketed predicate device K202952 Dental Glass Ceramics.