December 8, 2025

Shenzhen Xiangtong Co., Ltd.
Xue Gong
RA Manager
Rm. 101,301,701,801,Bldg. 1,#110,Guanchang Rd.
Dalingshan Town
Dongguan, Guangdong 523800
China

Re: K252789
Trade/Device Name: Glass Ceramic
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: September 2, 2025
Received: September 2, 2025

Dear Xue Gong:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

FDA Bobak Shirmohammadi -S

For Michael E. Adjodha, M.ChE., 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: 07/31/2026
*See PRA Statement below.*

510(k) Number *(if known)*
K252789

Device Name
Glass Ceramic

Indications for Use *(Describe)*
Glass Ceramic is used for the preparation of veneers, inlays, onlays, crowns, and three-unit bridges not involving molar restoration using hot press or CAD/CAM techniques.

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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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# 510(k) Summary

Date of Summary Preparation: August 29, 2025

This summary of 510(k) is being submitted in accordance with the requirements of 21 CFR Part 807.92.

The assigned 510(K) number is: **K252789**

## 1. Submitter's Identification

Submitter's name:SHENZHEN XIANGTONG CO.,LTD.

Address:Room 101,301,701,801,Building 1,No.110,Guanchang Road,Dalingshan Town,Dongguan,523800 Guangdong,P.R.China.

Tel: +86-0755-86001801 Email: xtcera@xianton.com Website:en.xtcera.com

Contact person:Xue Gong

Title:RA Manager Tel: +86-13760477635 Email:gongx@xianton.com

## 2. Device Identification

Type of 510(k) submission: Abbreviated

Device common name: Dental porcelain/ceramic

Device Name/Proprietary Name/Trade Name:Glass Ceramic

Classification Name: Porcelain powder for clinical use

Classification Regulation: 21 CFR 872.6660

Class: Class 2

Panel: Dental

Product code: EIH

## 3. Legally marketed predicate device

K230487, “Dental Lithium Disilicate Glass-Ceramic”, manufactured by “Fuzhou Rick Brown Biomaterials CO.,LTD.” (Primary predicate)

## 4. Indications for use

Glass Ceramic is used for the preparation of veneers, inlays, onlays, crowns, and three-unit bridges not involving molar restoration using hot press or CAD/CAM techniques.

## 5. Device Description

Glass Ceramic products are grouped into two main categories: CAD/CAM Glass Ceramic and Hot Press Glass Ceramic. CAD/CAM Glass Ceramic shapes include rectangular and customized shapes,

and Hot Press Glass Ceramic shapes include rectangular, cylinder, and customized shapes.

Glass Ceramic is available in 33 colors, and its performance conforms to ISO 6872 Dentistry: Ceramic Materials.

Glass Ceramic is composed of silicon dioxide, lithium oxide, potassium oxide, phosphorus pentoxide, aluminum oxide and other oxides.

This product is for prescription use only.

## 6. Substantially Equivalent Comparison

| Description | Subject device | Predicate device | Comment |
|---|---|---|---|
| 510(k) Owner | SHENZHEN XIANGTONG CO.,LTD. | Fuzhou Rick Brown Biomaterials CO.,LTD | --- |
| Device Name | Glass Ceramic | Dental Lithium Disilicate Glass-Ceramic | --- |
| Product code | EIH | EIH | Same |
| Regulation number | 21 CFR 872.6660 | 21 CFR 872.6660 | Same |
| Classification | Class 2 | Class 2 | Same |
| Indications for use | Glass Ceramic is used for the preparation of veneers, inlays, onlays, crowns, and three-unit bridges not involving molar restoration using hot press or CAD/CAM techniques. | Dental Lithium Disilicate Glass-Ceramic is available using CAD/CAM and hot pressing techniques for the preparation of full ceramic crowns, inlays, onlays, veneer and full ceramic 3-unit anterior bridges. | Same Differences in textual descriptions |
| Material | $SiO_2$, $Li_2O$, $K_2O$, $P_2O_5$, $Al_2O_3$ and other oxides | $SiO_2$, $Li_2O$, $K_2O$, $Al_2O_3$,$P_2O_5$, $ZrO_2$ and other oxides | Similar |
| Use | Prescription | Prescription | Same |
| Shape and Crystallization State as Supplied | Rectangular:Partially crystallized, final crystallization done by dental laboratory Cylinder:Fully crystallized | Cuboid:Partially crystallized, final crystallization done by dental laboratory Cylinder:Fully crystallized | Same Differences in textual descriptions |
| Shade | Various | Translucency: | Similar |

| | | | |
|---|---|---|---|
| | | High Translucency (HT)<br>Medium translucency(MT)<br>Low Translucency (LT)<br>Medium Opacity (MO)<br>High Opacity (HO)<br>Shades:<br>HT/MT/LT: 16 A-D<br>and 4 Bleach<br>MO: 5 MO 0 – MO 4<br>HO: 3 HO 0 – HO 2 | |
| Sterile | Non-sterile | Non-sterile | same |
| Single Use | Yes | Yes | same |
| Type, class of dental ceramic | Type II, Class 3 | Type II, Class 3 | same |
| Uniformity | Meet the requirements of ISO 6872 | Not Reported | The subject device meets ISO 6872 requirements |
| Freedom from | Freedom from extraneous materials | Freedom from extraneous materials | same |

| | | | |
|---|---|---|---|
| extraneous materials | | | |
| Radioactivity | Dental ceramic materials shall not have an activity concentration of more than 1.0 $Bq \cdot g^{-1}$ of 238 U | Meets ISO 6872 requirements ≤ 1.0 Bq/g of $^{238}U$ | same |
| Biaxial flexural strength | ≥300Mpa | ≥300Mpa | same |
| Chemical solubility | ＜100μg/$cm^2$ | ＜100μg/$cm^2$ | same |
| Fracture toughness | ≥2.0MPa·$m^{1/2}$ | Not Reported | The subject device meets ISO 6872 requirements |
| Linear thermal expansion coefficient | (10.5±0.5)×$10^{-6}K^{-1}$ | (9.8±0.5) x $10^{-6}$/K | Similar |
| Glass transition temperature | 555±20℃ | 495±20℃ | Different |
| Biocompatibility | Conform to ISO 10993-1 | Conform to ISO 7405: 2018 | Similar |

Different:

According to the standard ISO 6872:2024 “Dentistry - Ceramic Materials”, the glass transition temperature of the ceramics shall not deviate by more than 20℃ from the value stated by the manufacturer. The acceptance criteria for the subject device's glass transition temperature are 555±20℃.

The test results indicate that the glass transition temperature of the subject device meets the requirements of the FDA consensus standard.

Therefore, this difference does not raise a risk to safety and effectiveness.

## 7. Non-Clinical performance data

Test data to support the evaluation of the subject device Glass Ceramic have been submitted and included by reference as follows:

- Product performance testing per ISO 6872, Dentistry - Ceramic materials.
- Biocompatibility assessment as follows:
  - ✧ Evaluation per ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.
  - ✧ Genotoxicity assessment per ISO 10993-3, Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity.
  - ✧ Cytotoxicity assessment per ISO 10993-5, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity.
  - ✧ Sensitization assessment per ISO 10993-10, Biological evaluation of medical devices - Part 10: Tests for skin sensitization.
  - ✧ Toxicity assessment per ISO 10993-11, Biological evaluation of medical devices - Part 11: Tests for systemic toxicity.
  - ✧ Irritation assessment per ISO 10993-23,Biological evaluation of medical devices - Part 23: Tests for irritation.

## 8. Substantial equivalence conclusion

The subject device, “Glass Ceramic,” and the predicate device, "Dental Lithium Disilicate Glass-Ceramic," have the same indications for use and similar technological characteristics.
Both the subject and predicate devices have been tested according to the same ISO 6872 (Dentistry-Ceramic materials) standard and met the same specification requirements of Type II, Class 3 materials.
The difference between the subject device and its predicate device does not raise any question regarding its equivalence.
The conclusions drawn from the nonclinical tests demonstrate that the subject device is as safe, as effective, and performs as well as the legally marketed predicate device. This shows that the subject device and the predicate device are substantially equivalent.