February 10, 2023

Shenzhen Xiangtong Co.,Ltd.
% Ray Wang
Gerneral Manager
Beijing Believe-Med Technology Service Co., Ltd.
Rm.912, Building #15, XiYueHui, No.5, YiHe North Rd.,
FangShan District
Beijing, Beijing 102401
CHINA

Re: K223194
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: December 12, 2022
Received: December 12, 2022

Dear Ray 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 -S

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)*

K223194

Device Name
Glass Ceramic

Indications for Use *(Describe)*
Glass Ceramic are indicated for fabricating all-ceramic restorations such as veneers, inlays, onlays, crowns, 2-unit anterior bridges, using the CAD/CAM system.

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.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# 510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) Number: K223194

1. Date of Preparation: 12/21/2022

2. Sponsor

**SHENZHEN XIANGTONG CO.,LTD.**
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3. Submission Correspondent

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4. Proposed Device Identification

Trade Name: Glass Ceramic
Common Name: Powder, Porcelain
Regulatory Information:
Classification: II
Product Code: EIH
Regulation Number: 21 CFR 872.6660

Regulation Name: Porcelain powder for clinical use
Review Panel: Dental

Indication For Use Statement:
Glass Ceramic is indicated for fabricating all ceramic restorations such as veneers, inlay/ onlay, partial crowns, anterior crowns, posterior crowns, using the CAD/CAM system.

5. Device Description

Glass Ceramic is indicated for fabricating all ceramic restorations such as veneers, inlay/ onlay, partial crowns, anterior crowns, posterior crowns, using the CAD/CAM system.

The Glass Ceramic is composed of SiO2, Li2O, K2O, P2O5, Al2O3 and other oxides, the performance of the Glass Ceramic conforms to ISO 6872: 2015 Dentistry: Ceramic Materials.

The Glass Ceramic is disposable device, and provided as non-sterile.

6. Predicate Device Identification

**Predicate Device:**
510(k) Number: K141727
Product Name: Dental Lithium Disilicate Glass Ceramic Block (Up. Press Series and Up. CAD Series)
Manufacturer: Liaoning Upcera Co., Ltd

**Reference Device:**
510(k) Number: K051705
Product Name: IPS E.MAX CAD
Manufacturer: Ivoclar Vivadent AG

7. Non-Clinical Test Conclusion

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 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 device - Part 5: Tests for in vitro cytotoxicity

- ISO 10993-10: 2021 Biological evaluation of medical devices - Part 10: Tests for skin sensitization
- ISO 10993-11: 2017 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
- ISO 10993-23: 2021 Biological evaluation of medical devices - Part 23: Tests for irritation
- ISO 6872: 2015 Dentistry - Ceramic materials

8. Clinical Test Conclusion

No clinical study is included in this submission.

9. Substantially Equivalent (SE) Comparison

Table 5-1 General Comparison

| ITEM | **Proposed Device (K223194)** | **Predicate Device (K141727)** Dental Lithium Disilicate Glass Ceramic Block (Up. CAD Series) | Remark |
|---|---|---|---|
| Product Code | EIH | EIH | SAME |
| Regulation No. | 21 CFR 872.6660 | 21 CFR 872.6660 | SAME |
| Class | II | II | SAME |
| Indication for Use | Glass Ceramic is indicated for fabricating all ceramic restorations such as veneers, inlay/ onlay, partial crowns, anterior crowns, posterior crowns, using the CAD/CAM system. | Dental Lithium Disilicate Glass Ceramic Blocks (Up. Press Series and Up. CAD Series) are indicated for fabricating all ceramic restorations such as veneers, inlay/ onlay, partial crowns, anterior crowns, posterior crowns, using the hot press technique or CAD/CAM system. | SIMILAR |
| Materials | SiO2, Li2O, K2O, P2O5, Al2O3 and other oxides | SiO2, Li2O, K2O, P2O5, Al2O3, B2O3, and other oxides | SIMILAR |
| Summary of sizes and shapes | Various | Various | SAME |
| Shade | Various | Various | SAME |
| Single Use | Yes | Yes | SAME |
| Principle of operation | CAD/CAM | CAD/CAM (Up. CAD Series) | SAME |
| Sterile | Non-sterile | Non-sterile | SAME |

Table 5-2 Performance Comparison

| **ITEM** | **Proposed Device** K223194 | **Predicate Device** K141727 | **Reference Device** K051705 | Requirement of ISO 6872 | **Remark** |
|---|---|---|---|---|---|
| Uniformity | Conformance to requirements | Conformance to requirements | Conformance to requirements | The inorganic pigment(s) used to produce the colour of a fired dental ceramic and any organic colorants (for colour coding) shall be uniformly dispersed throughout the dental ceramic material and in powdered ceramic products, no segregation of the pigment(s) shall take place when the powder is mixed as in ISO 6872:2015 7.1.3.Check by visual inspection. | SAME |
| Freedom from extraneous materials | Conformance to requirements | Conformance to requirements | Conformance to requirements | Dental ceramic materials shall be free from extraneous materials when assessed by visual inspection. | SAME |
| Radioactivity | < 1.0Bq·g¹ of $^{238}U$ | < 1.0Bq·g¹ of $^{238}U$ | < 1.0Bq·g¹ of $^{238}U$ | Dental ceramic materials shall not have an activity concentration of more than 1.0Bq·g¹ of $^{238}U$. Test in accordance with ISO6872:2015 7.22. | SAME |
| Biaxial flexure | 308.4MPa | / | 530MPa | Type II Class2 ＞100MPa | Different 1 |
| Linear thermal expansion coefficient | $10.8\times10^{-6}K^{-1}$ | $(8.5\text{-}11)\times10^{-6}K^{-1}$ | / | The coefficient of thermal expansion of the ceramics shall not deviate by more than $0{,}5\times10^{-6}K^{-1}$ from the value stated by the manufacturer. | SIMILAR |
| Glass transition temperature | 553.5℃ | / | / | The glass transition temperature of the ceramics shall not deviate by more than 20 °C from the value stated by the manufacturer. | Different 2 |
| Chemical solubility | $9.5\mu g\cdot cm^{-2}$ | ＜$100\mu g\cdot cm^{-2}$ | / | Type II Class2 ＜$100\mu g\cdot cm^{-2}$ | SIMILAR |
| Fracture toughness | 3.83MPa√m | / | 2.11MPa√m | Type II Class2 ＞1MPa√m | Different 3 |

Note: " / " means that it cannot be got.

Different 1:

The proposed device is different from K051705 on biaxial flexure strength, the proposed device is Type 2 Class 2. According to ISO 6872, the biaxial flexure strength of Type 2 Class 2 should be greater than 100MPa. We have conducted performance tests, and the test results show that Glass Ceramic can meet the requirements of Type 2 Class 2, so this difference does not increase any risk of effectiveness.

Different 2:

We cannot get the glass transition temperature of predicate device, so the proposed device may be different from predicate device on glass transition temperature. According to ISO 6872, the glass transition temperature of the ceramics shall not deviate by more than 20°C from the value stated by the manufacturer. The glass transition temperature of ceramics specified by us is 555℃, and the test results of ISO 6872 show that the deviation does not exceed 20°C, so this difference does not increase any risk of effectiveness.

Different 3:

The proposed device is different from K051705 on fracture toughness. According to ISO 6872, the Fracture toughness of Type 2 Class 2 should be greater than 1MPa√m. We have conducted performance tests, and the test results show that Glass Ceramic can meet the requirements of Type 2 Class 2 and the proposed device is better than K0511705 on fracture toughness, so this difference does not increase any risk of effectiveness.

Table 5-3 Biocompatibility Comparison

| ITEM | **Proposed Device** (K223194) | **Predicate Device** (K141727) | Standard | **Remark** |
|---|---|---|---|---|
| Cytotoxicity (Agar diffusion) | Conformance to requirements | Conformance to requirements | ISO 10993-5 | SAME |
| Sensitization | Conformance to requirements | Conformance to requirements | ISO 10993-10 | SAME |
| Acute systemic toxicity (Oral) | Conformance to requirements | Conformance to requirements | ISO 10993-11 / ISO 10993-23 | SAME |
| Oral mucosa irritation | Conformance to requirements | Conformance to requirements | ISO 10993-10 | SAME |
| Bacterial reverse mutation (Ames test) | Conformance to requirements | Conformance to requirements | ISO 10993-3 | SAME |

10. Substantially Equivalent (SE) Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device (K141727).