March 27, 2023

Shenzhen Xiangtong Co.,Ltd.
Xue Gong
Regulatory affairs
2nd Floor, 1st Building, West Area, Honghualing Industrial
Park, No.88, North Zhuguang Rd
Shenzhen, Guangdong 518055
CHINA

Re: K223192
Trade/Device Name: XT Stain/Glaze
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: December 27, 2022
Received: December 27, 2022

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 (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
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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)*

K223192

Device Name
XT Stain/glaze

Indications for Use *(Describe)*
XT stain/glaze are glazing porcelains used to color staining and glazing of the surfaces of dental ceramic restorations,such as glass ceramic or zirconia-based ceramic.

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

Date of Summary Preparation: March 24, 2023

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

The assigned 510(k) Number: **K223192**

1. Submitter's identifications

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

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

2. Correspondent's identifications

Contact person:Xue Gong

Title:Regulatory supervisor

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Or,

Other contact person:Rose

Tel: +86-15989372253 Email:Rose@xianton.com

3. Device information

Type of 510(k) submission: Traditional

Device common name: Dental porcelain/ceramic

Device Name/Proprietary Name/Trade Name:XT stain/glaze

Classification Name: Porcelain powder for clinical use

Classification Regulation: 21 CFR 872.6660

Class: Class 2

Panel: Dental

Product code: EIH

4. Legally marketed predicate device

Primary Predicate device: K181167, "Glaze Paste, Glaze Powder, and Glaze Liquid", manufactured by "Liaoning Upcera Co., Ltd."

Reference device:

K202629, "Dentsply Sirona Universal Spray Glazes", manufactured by "Dentsply Sirona"

Reference device support the substantial equivalence of the glaze spray in the subject device.

5. Device description

XT stain/glaze includes glaze powder,glaze liquid,stain glaze,glaze spray.

Glaze powder is composed primarily of SiO_2,with components of B_2O_3,Al_2O_3, Na_2O,K_2O,Li_2O, other oxides,and color additives.

Glaze liquid is composed of deionized water and organic solvents.

Stain glaze is mixed with glaze powder and glaze liquid,which can help dental professionals save the mixing process.It is in the form of a paste and applied to dental ceramic restoration surfaces by brushing.Glaze powder has 17 colors; therefore, glaze paste also has 17 colors.

Glaze spray consists of glaze powder(Transparent-Glaze),organic solvent,deionized water, and Non-CFC propellant.It is supplied to dental professionals in the form of an aerosol can and applied to dental ceramic restoration surfaces by spraying.

Glaze spray and stain glaze require the firing of the dental ceramic restorations after application of the glaze. During the firing process, the organic solvent and deionized water burn without being included in the dental ceramic restorations. Therefore, the final chemical composition of the dental ceramic restorations is the glaze powder.

6. Indications for use

XT stain/glaze are glazing porcelains used to color staining and glazing of the surfaces of dental ceramic restorations,such as glass ceramic or zirconia-based ceramic.

7. Substantial equivalence comparison

Description	Subject device(K223192)	Predicate device(K181167)	Reference device(K202629)	Comment
Manufacturer	SHENZHEN XIANGTONG CO.,LTD.	Liaoning Upcera Co., Ltd.	Dentsply Sirona	None
Proprietary name	XT stain/glaze	Glaze Paste, Glaze Powder, and Glaze Liquid	Dentsply Sirona Universal Spray Glazes	None
Product code	EIH	EIH	EIH	Same
Regulation number	21 CFR 872.6660	21 CFR 872.6660	21 CFR 872.6660	Same
Classification	Class 2	Class 2	Class 2	Same
Indication for use	XT stain/glaze are glazing porcelains used to color staining and glazing of the surfaces of dental ceramic restorations,such as glass ceramic or zirconia-based ceramic.	“Glaze Paste, Glaze Powder, and Glaze Liquid” are indicated for use as a veneering material for fixed prosthesis in crowns and bridges. This device is used in prosthetic dentistry by forming a porcelain veneer on to a ceramic substructure.	Dentsply Sirona Universal Spray Glazes are aerosol glazing porcelains used to glaze high strength glass ceramic and zirconia dental restorations. The glaze sprays are applied to restorations and fired.	Same See 7(1) for explanatory notes

Form	Paste, spray,liquid, and powder	Paste, liquid, and powder	Spray	Similar to reference device See 7(2) for explanatory notes
Application	Brushing ,spraying	Brushing	The glaze is applied by spraying on to the surface of the dental restorations and a firing process is carried out in a dental furnace.	Similar to reference device See 7(2) for explanatory notes
Composition	SiO_2,B_2O_3,Al_2O_3,Na_2O,K_2O, Li_2O,etc Glaze spray contains organic solvent, deionized water, and Non-CFC propellent that is burned off during the firing process and is not included in the dental ceramic restorations.	SiO_2, Al_2O_3, K_2O, Na_2O, Li_2O, etc	Major components: oxides(silicate glass) Device contains organic components and propellent that is burned-off during the firing process and is not included in the final device.	Similar See 7(3) for explanatory notes
Type, class of dental ceramic	Type I - Class I	Type I - Class I	Type I - Class I	Same
Use	Prescription	Prescription	Prescription	Same

Single Use	Yes	Yes	Yes	Same
Feature	Various colors	Various colors	Various colors	Same
Sterile	Non-sterile	Non-sterile	Non-sterile	Same
Packaging components	Plastic bottle,aerosol can with propellent	Not publicly available	Packaged in a spray can with cap	Different See 7(4) for explanatory notes
Shelf life/ Storage	3 years The packaged product shall be stored in a room where there is good ventilation, avoid strong sunlight, and without corrosive gas,temperature not more than 45℃ .Keep the package intact and upward during storage.	Not publicly available	3.5 years Avoid exposure to temperatures exceeding 50°C / 122 °F.	Different See 7(5) for explanatory notes
Physical properties	Meet the requirements of ISO 6872,USP 43-NF38:2020 1.Uniformity 2.Freedom of extraneous materials	Meet the requirements of ISO 6872 1.Flexural strength 2.Transition temperature 6.Thermal expansion 4.Radadiopacity	Meet the requirements of ISO 6872 1.Uniformity 2.Freedom of extraneous materials 3.Flexural strength	Similar The performance of the subjiect device includes predicate device and reference device.

	3.Mixing and condensation 4.Flexural strength 5.Chemical solubility 6.Linear thermal expansion coefficient 7.Radadiopacity 8.Glass transition temperature 9.Heavy metal		4.Chemical solubility 5.Linear thermal expansion coefficient 6.Radadiopacity 7.Glass transition temperature	
Biocom-patibility	Meet the requirements of ISO 10993-1,-3,-5,-10,-11	Meet the requirements of ISO 10993-1,-3,-5,-10,-11	Conform to ISO 7405 and ISO 10993-1,-5	Similar We performed ISO 10993 test to prove our product's biocompatibility.

Notes:

(1)Indication for use

Subject device and predicate device:

a.The main role of the veneering material is color staining and glazing.Glazing porcelains belong to veneering material.

b.Prosthesis and restorations are only descriptive differences.

c.Glass ceramic and zirconia-based ceramic belong to ceramic substructure.

The subject device XT stain/glaze and the predicate device have the same use, XT stain/glaze is worded differently for simplification.

Compared with the predicate device, the subject device has a slightly different phrasing of potential dental applications in the Indications for Use Statement. This difference in wording is minor, and the subject device complies with the recommended clinical indications in Table 1 of ISO 6872: 2015.

The subject device and reference device have the same use and only the wording differs. Reference device is only one type of spray glaze form.

(2)Form

For restorations that don't require color finishing, brushing stain glaze (color:Transparent-Glaze) or spraying glaze spray (color:Transparent-Glaze) directly.

Paste and sprays are designed according to usage habits.The glaze spray in an aerosol form decreases the in-process time of hand-applied glazing methods and for ease of use in dental laboratories.

(3)Composition

The final chemical composition of the dental ceramic restorations is the glaze powder.

Subject device(glaze powder,glaze liquid,stain glaze) and predicate device(Glaze Paste, Glaze Powder, and Glaze Liquid):

The subject and predicate device have slight difference in composition. But they both have silicate glass and oxides as the major component.The minor differences don't raise any additional questions for safety and effectiveness.And the biocompatibility testing of the overall proposed device passed.

Subject device(glaze spray) and reference device(Dentsply Sirona Universal Spray Glazes):

Both devices consist of refined aerosol delivery systems used to apply the glaze. They have the same working principle in that the glaze is applied by a spray jet onto the restoration and a firing process is carried out to melt the glaze. Both devicess use Non-CFC propellants to eject the contents.

The main composition of both devices are similar. The silicate glass,organic solvent, wetting agents(deionized water), and Non-CFC propellent are similar.The final device contains only silicates, the other components burned off during the firing process.

(4)Packaging components

The packaging of glaze spray is the same as the reference device. Transport and package testing were performed on plastic bottle and aerosol can according to ISTA 3A and the standards referenced therein.

(5)Shelf life/ Storage

Evaluation of shelf life per ASTM F1980.Storage conditions for subject device within the range of reference device.

The subject device and the predicate devices have the same indication for use, biocompatibility properties, and similar design, material, physical, and chemical properties. The non-clinical test results show that the minor differences don’t raise additional questions about safety and effectiveness.

8. Non-Clinical performance data

Test data to support the evaluation of the subject device XT stain/glaze have been submitted and included by reference as follows:

- Product heavy metal testing per USP 43-NF 38:2020<233> ,other 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 and irritation assessment per ISO 10993-10, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.
  - ✧ Toxicity assessment per ISO 10993-11, Biological evaluation of medical devices - Part 11: Tests for systemic toxicity.
- Transport and package testing per ISTA 3A and the standards referenced therein.
- Evaluation of shelf life per ASTM F1980, Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.

9. Clinical performance data

No data from human clinical studies has been included to support the substantial equivalence of the subject device, XT stain/glaze.

10. Substantial equivalence conclusion

The subject device XT stain/glaze and the predicate device "Glaze Paste, Glaze Powder, and Glaze Liquid" have the same indication for use as glazing materials, incorporate the same fundamental techniques, and have similar significant components.

Both the predicate and subject devices have similar technological characteristics and were tested to the same ISO 6872:2015 (Dentistry-Ceramic materials) standard and met the same specification requirements of Type I Class 1 materials.

The difference between the subject device and its predicate device do not raise any question regarding its equivalence.

The comparative information, combined with the design and intended use comparison with the predicate device, support substantial equivalence to the subject device XT stain/glaze.