Liaoning Upcera Co., Ltd
% Charles Shen
Director
Manton Business and Technology Services
37 Winding Ridge
Oakland, New Jersey 07436

September 2,2018

Re: K181167
Trade/Device Name: Upcera Glaze Paste, Glaze Powder, and Glaze Liquid
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain powder for clinical use
Regulatory Class: Class II
Product Code: EIH
Dated: June 2, 2018
Received: June 5, 2018

Dear Charles Shen:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mary S. Runner -S

For Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K181167

Device Name
Glaze Paste, Glaze Powder, and Glaze Liquid

Indications for Use *(Describe)*
"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.

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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"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."

Section 5: 510(k) Summary:

This summary of 510k safety and effectiveness information is being submitted
In accordance with the requirements of 21CFR 807.92

5.1 Submitter & Foreign Manufacture Identification

Liaoning Upcera Co., Ltd
No.122 Xianghuai Road, Economic Development Zone, Benxi, Liaoning, China
Tel：(086)-24-45565006
Submitter's FDA Registration Number：3010582952
www.upcera-dental.com

5.2 Contact Person

Charles Shen
Manton Business and Technology Services
37 Winding Ridge, Oakland, NJ 07436
Tel: 608-217-9358
Email: cyshen@aol.com

5.3 Date of Summary: June 5, 2018

5.4 Device Name:

Proprietary Name:	Glaze Paste, Glaze Powder, and Glaze Liquid
Common Name:	Dental Ceramics
Classification Name:	Porcelain powder for clinical use
Device Classification:	II
Regulation Number:	21 CFR 872.6660
Panel:	Dental
Product Code:	EIH

5.5 Predicate Device Information:

(1) K151731, "rainbow Paste Stain", manufactured by "GENOSS Co., Ltd."

5.6 Device Description:

"Glaze Paste, Glaze Powder, and Glaze Liquid" is a dental veneering material used for color staining and glazing of the surfaces of restorations such as porcelain-fused zirconia, full-contoured zirconia, or lithium disilicate. The intended use of general porcelain is to make the artificial teeth (dental prosthesis) more similar with natural teeth.

"Glaze Paste, Glaze Powder, and Glaze Liquid" are actually three products: Powder, paste, and liquid. "Glaze Powder" is in the form of a porcelain dry powder and liquid.

When mixed together by the technician at a dental lab, they form the paste stain before applied to the patient.

"Glaze Paste" is pre-mixed paste from porcelain powder and liquid, which can help dental technicians save the mixing process.

The porcelain powder is composed primarily of SiO_2, with minor components of Al_2O_3, K_2O, Na_2O, Li_2O, and color additives. The liquid is composed of deionized water and organic solvents. The liquid can also be used as a thinner to control viscosity of paste.

"Glaze Paste, Glaze Powder, and Glaze Liquid" are supplied in seventy one different colors, with or without fluorescence effect.

The performance of material conforms to *ISO 6872, Dentistry, Ceramic Materials.*

5.7 Indications for Use:

"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.

5.8 Summary of Device Testing:

Bench testing was performed per ISO 6872:2015 and internal procedures to ensure that the "Glaze Paste, Glaze Powder, and Glaze Liquid" met its specifications. All tests were verified to meet acceptance criteria. Biocompatibility testing was performed to verify the equivalence of the materials that are used.

5.9 Technological Comparison with Predicate Device

The following table shows similarities and differences of use, design, and material between our device and the predicate devices.

Table 5.1: Comparison of Intended Use, Design, Material, and Processing

Description	Subject Device	Predicate Device (K151731)
Indication for Use	"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.	rainbow Paste Stain is 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.
Form	Paste, liquid, and powder	Paste
Materials	SiO_2, Al_2O_3, K_2O, Na_2O, Li_2O, etc	Feldspar, SiO_2, Na_2CO_3, K_2CO_3, Li_2CO_3, $CaCO_3$, ZnO, etc.
Type, class of dental ceramic	Type I - Class I	Type I - Class I
Use	Prescription	Prescription
Single Use	Yes	Yes
Feature	Various colors	Various colors
Sterile	Non-sterile	Non-sterile

Our device is essentially identical to the predicate device in terms of indications for use, design, material, and processing between our device and the predicate devices. The minor differences do not raise any safety or efficacy concerns.

5.10 Comparison of Performance with Predicate Device

Performance testing was performed on the subject device and results were compared with predicate device. Tests were conducted following applicable procedures outlined in the FDA recognized consensus standard of ISO 6872, and results met all relevant requirements in the test standard. Test results on radioactivity, transition temperature, thermal expansion, and flexural strength of the subject device are very similar to the predicate device.

The following table shows similarities and differences of the biocompatibility between our device and the predicate devices. Tests were conducted following the recommended procedures outlined in the FDA recognized consensus standard of ISO 10993, and results met all relevant requirements in the test standards, and are comparable to the predicate device.

Table 5.2: Comparison of Biocompatibility Testing

Description	Subject Device	Predicate Device (K151731)
Cytotoxicity (ISO 10993-5:2009)	No cyteotoxicity effect	No cyteotoxicity effect
Irritation Oral Mucosa Irritation (ISO 10993-10: 2010)	Not a primary oral mucosa irritant under the conditions of the study	No intracutaneous reactivity
Sensitization (ISO 10993-10: 2010)	Not a sensitizer under the conditions of the study	Not a sensitizer under the conditions of the study
Acute Toxicity (ISO 10993-11: 2006)	No acute toxic effects observed	No acute toxic effects observed
Subacute and Subchronic Toxicity (ISO 10993-11: 2006)	No subacute and subchronic toxic effects observed	Not performed
Genotoxicity (ISO 10993-3: 2003)	No genotoxic effects observed	No genotoxic effects observed

Therefore, "Glaze Paste, Glaze Powder, and Glaze Liquid" manufactured by "Liaoning Upcera Co., Ltd." meet requirements per ISO 6872 and ISO 10993-1. The test results are also comparable to the predicate device.

5.11 Substantial Equivalence Conclusion

It has been shown in this 510(k) submission that "Glaze Paste, Glaze Powder, and Glaze Liquid" and its predicate devices have the identical indications for use, similar composition and biocompatibility, similar manufacturing process, and similar performance.

The difference between the "Glaze Paste, Glaze Powder, and Glaze Liquid" and its predicate device do not raise any question regarding its equivalence.

"Glaze Paste, Glaze Powder, and Glaze Liquid", as designed and manufactured, is equivalent to its predicate device, and therefore is substantially equivalent as its predicate device.