June 29, 2022

Dongguan Xiangtong Co., Ltd.
Charles Shen
Director
Manton Business and Technology Services
37 Winding Ridge
Oakland, New Jersey 07436

Re: K220017
Trade/Device Name: Coloring Liquid
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: May 28, 2022
Received: June 3, 2022

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/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, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K220017

Device Name
Coloring Liguid

Indications for Use *(Describe)*
Coloring Liquid is a liquid used for the complete or partial coloration of milled zirconia substructure and anatomy before sintering.

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.

Section 5: 510(k) Summary:

K220017

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

DONGGUAN XIANGTONG CO., LTD
NO.4, Tech 9th Rd, Hi-Tech Industrial Development Zone, Songshan Lake, Dongguan, Guangdong, China., Zipcode 523000
Tel： (086)-0769-22895688
Submitter's FDA Registration Number： N/A

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: December 19, 2021

5.4 Device Name:

Proprietary Name:	Coloring Liquid
Common Name:	Coloring Liquid
Classification Name:	Powder, Porcelain
Device Classification:	II
Regulation Number:	21 CFR 872.6660
Panel:	Dental
Product Code:	EIH

5.5 Predicate Device Information:

(1) K141723, "Upcera Coloring Liquid (I and II)", manufactured by "Liaoning Upcera Co., Ltd." located in Benxi, China

5.6 Device Description:

Coloring Liquid is water based, which consist of watery, acidic metal salt solutions. They are used for the individual staining of dental zirconia frameworks and restorations prior to the final sintering of the restoration, enabling the user to adjust the restoration to match the natural color of the patient's teeth.

Coloring Liquid is provided in 45 different shades, which are corresponding to patient's closest tooth color. For staining, the zirconia materials have to be immerged into the liquids or to be brushed with the liquids, prior to sintering at high temperatures

5.7 Indications for Use:

Coloring Liquid is a liquid used for the complete or partial coloration of milled zirconia substructure and anatomy before sintering.

5.8 Summary of Device Testing:

Bench testing was performed to ensure that the Coloring Liquid met its specifications. All tests were verified to meet acceptance criteria. Biocompatibility testing was performed to verify the equivalent safety of the materials that are used.

5.9 Comparison With Predicate Device

Coloring Liquid is compared with the following Predicate Devices in terms of intended use, design, material, specifications, and performance.

(1) K141723, "Upcera Coloring Liquid (I and II)", manufactured by "Liaoning Upcera Co., Ltd." located in Benxi, China

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 (K141723)
Indication for Use	Coloring Liquid is a liquid used for the complete or partial coloration of milled zirconia substructure and anatomy before sintering.	Upcera Coloring Liquid (I and II) is a liquid used for the complete or partial coloration of milled Upcera zirconia substructure and anatomy before sintering.
Technology	Water based with inorganic pigments	Water based with inorganic pigments
Operating Principle	Brush or immerse zirconia ceramic materials with coloring liquid before sintering	Brush or immerse zirconia ceramic materials with coloring liquid before sintering
Ingredient	Water, Polyethylene glycol, inorganic salts	Water, Polyethylene glycol, inorganic salts
Bottle Size	Various	Various
Shade	Various	Various
Prescription	Yes	Yes

Sterile	Non-sterile	Non-sterile

The subject device is similar to the predicate device in terms of indications for use, technology, and principle of operation.

The following table shows similarities and differences of the safety tesing between our device and the predicate devices.

Table 5.2: Comparison of Safety Testing

Description	Subject Device	Predicate Device (K141723)
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	Not a primary oral mucosa irritant under the conditions of the study
Sensitization (ISO 10993-10: 2010)	Not a sensitizer under the conditions of the study	Not a sensitizer under the conditions of the study
Acute Systemic Toxicity and Subchronic Toxicity (ISO 10993-11: 2006)	No Acute Systemic Toxicity and subchronic toxic effects observed	No acute and subchronic toxic effects observed
Genotoxicity (ISO 10993-3: 2003)	No genotoxic effects observed	No genotoxic effects observed

5.10 Non-clinical Testing

Non-clinical Testing Bench testing was performed to ensure the Coloring Liquid met its specifications. All tests were verified to meet acceptance criteria. Biocompatibility testing was performed to verify the substantially equivalent safety of the materials that are used.

5.11 Conclusions

It has been shown in this 510(k) submission that “Coloring 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 “Coloring Liquid” and their predicate device do not raise any question regarding its equivalence.

“Coloring Liquid”, as designed and manufactured, is substantially equivalent as its predicate device.