August 18, 2020

Aidite (Qinhuangdao) Technology Co., Ltd.
% Christy Young
Consultant
Shenzhen Joyantech Consulting Co., Ltd
NO. 55 Shizhou Middle Road, Nanshan District
Shenzhen, 518000 CHINA

Re: K192723
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 12, 2020
Received: May 20, 2020

Dear Christy Young:

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,

for Srinivas “Nandu” Nandkumar, Ph.D.
Director
DHT1B: Division of Dental 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)*
K192723

Device Name
Coloring Liquid

Indications for Use *(Describe)*
Coloring Liquid is a liquid used for the complete or partial coloration of zirconia ceramic materials.

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

K192723

1. Contact Details

1.1 Applicant information

Applicant Name	Aidite (Qinhuangdao) Technology Co., Ltd.
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Date Prepared	Aug 18, 2020
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1.2 Submission Correspondent

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Contact person's e-mail	christy@cefda.com;field@cefda.com
Website	http://www.cefda.com

2. Device information

Trade name	Coloring Liquid
Common name	Coloring Liquid
Model	/
Classification	Ⅱ
Classification name	Porcelain Powder for Clinical use
Product code	EIH
Regulation No.	872.6660

3. Legally Marketed Predicate Device

Trade Name	Upcera Coloring Liquid (I and II)
510(k) Number	K141723 (Primary Predicate Device)
Product Code	EIH
Manufacturer	Liaoning Upcera Co., Ltd

4. Device Description

Coloring liquid are water-based coloring liquids, 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.

For staining, the zirconia materials have to be immerged into the liquids or to be brushed with the liquids, prior to sintering at high temperature.

5. Intended Use/Indication for Use

Coloring Liquid is a liquid used for the complete or partial coloration of zirconia ceramic materials.

6. Substantial Equivalence Comparison

Item	**Proposed Device: Coloring Liquid**	**Primary Predicate Device: Upcera Coloring Liquid (I and II) (K141723)**	**Comments**
Product Code	EIH	EIH	Same
Intended Use	Coloring Liquid is a liquid used for the complete or partial coloration of zirconia ceramic materials.	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.	Same
Technology	Water based with inorganic pigments	Water based with inorganic pigments	Same
Operating Principle	Brush or immerse zirconia ceramic materials with coloring liquid before sintering	Brush or immerse zirconia ceramic materials with coloring liquid before sintering	Same
Ingredient	Water, polyethylene glycol, Polydextrose, inorganic salts	Upcera Coloring Liquid I: Water, Polyethylene glycol, HCl, inorganic salts Upcera Coloring Liquid II: Water, Polydextrose, inorganic salts	Similar, Note 1
Bottle size	Various	Various	Same
Shade	Various	Various	Same
Sterile	Non-sterile	Non-sterile	Same
Cytotoxicity (ISO 10993-5:2009)	No cytotoxicity effect	No cytotoxicity effect	Same
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	Same
Sensitization(ISO	Not a sensitizer under the conditions of the study	Not a sensitizer under the conditions of the study	Same

10993-10:2010)			
Subchronic Toxicity(ISO 10993-11:2006)	No subchronic toxic effects observed	No subchronic toxic effects observed	Same
Genotoxicity (ISO10993-3:2003)	No genotoxic effects observed	No genotoxic effects observed	Same

Note 1:

It is similar with the predicate device that water, Polydextrose and inorganic salts are the main ingredients. The minor difference between the proposed device and the predicate device, Upcera Coloring Liquid II, is that the proposed device contains polyethylene glycol. Polyethylene glycol, which is also a ingredient of the predicate device Upcera Coloring Liquid I, is a safe dispersant and does not react with the other ingredients. This difference will not cause any safety issues and we have conducted biocompatibility testing with the products.

7. 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.

8. Conclusion

It has been shown in this 510(k) submission that Coloring Liquid and its predicate devices have the similar indications for use, technology, principle of operation, similar composition and biocompatibility.

The difference between Coloring Liquid and its predicate device do not raise any question regarding its safety and effectiveness.

Coloring Liquid, as designed and manufactured, is as safe and effective as its predicated device, and therefore is substantially equivalent as its predicate device.