December 17, 2020

Aidite (Qinhuangdao) Technology Co., Ltd.
℅ Jessie You
Official Correspondent
Shenzhen Joyantech Consulting Co., Ltd
NO. 55 Shizhou middle road , Nanshan District
Shenzhen, GD755 CHINA

Re: K190217
Trade/Device Name: Aidite Pmma
Regulation Number: 21 CFR 872.3770
Regulation Name: Temporary Crown and Bridge Resin
Regulatory Class: Class II
Product Code: EBG
Dated: November 26, 2020
Received: December 4, 2020

Dear Jessie You:

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 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)*
K190217

Device Name
Aidite Pmma

Indications for Use *(Describe)*
The device is made from PMMA (polymethylmethacrylate) for the fabrication of temporary crowns and bridges and is intended for use in the oral cavity for up to six (6) months while awaiting a permanent restoration. Restorations are designed and manufactured by a dental Professional (Technician) using CAD technology.

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

1. Submission Sponsor

Applicant Name	Aidite (Qinhuangdao) Technology Co., Ltd.
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Date Prepared	2020-12-10

2. Submission correspondent

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Phone No.	86-755-86069197
Contact Person	Mr. Field Fu; Ms. Jessie You; Ms. Elly Xu
Email	Jessie@cefda.com; Elly@cefda.com

3. Devices Identification

Trade name	Aidite Pmma
Models	Cylinder and Cuboid
Device class	II
Classification name	Crown and Bridge, Temporary, Resin
Product code	EBG
Regulation number	21 CFR 872.3770
Regulation description	Temporary crown and bridge resin
Regulation medical specialty	Dental

4. Legally Marketed Predicate Devices

Trade name	PMMA Block
510(K) Number	K141421
Manufacturer	Rizhao Huge Dental Industry Co., Ltd
Device class	II

Classification name	Crown and Bridge, Temporary, Resin
Product code	EBG
Regulation number	21 CFR 872.3770
Regulation description	Temporary crown and bridge resin
Regulation medical specialty	Dental

5. Device Description

The Aidite Pmma is a homogeneous high polymer material made from PMMA (polymethylmethacrylate) added with cross-linking agents to improve the network structure through a unique polymerization molding technology. The device is for the fabrication of temporary crowns and bridges and is intended for use in the oral cavity for up to six months while awaiting a permanent restoration. Restorations are designed and manufactured by a dental professional (such as a dentist) using CAD technology.

The proposed device contains two models with different shape: Cylinder and Cuboid. There are 40 specifications for Cylinder model (variation in different diameters and heights), and 24 specifications for Cuboid model (variation in different lengths, widths, and heights).

There are 17 various shades of the proposed device: 1 is transparent (without color added), the other 16 shades are colored (with different coloring matters added). The 16 shades created based on 16 Vita Shades contain A1, A2, A3, A3.5, A4, B1, B2, B3, B4, C1, C2, C3, C4, D2, D3, and D4.

The Aidite Pmma would be produced on the 40 specifications of Cylinder model or 24 specifications of Cuboid model, with a shade chosen from the 17 various shades.

6. Indications for Use Statement

The device is made from PMMA (polymethylmethacrylate) for the fabrication of temporary crowns and bridges and is intended for use in the oral cavity for up to six (6) months while awaiting a permanent restoration. Restorations are designed and manufactured by a dental Professional (Technician) using CAD technology.

7. Substantial Equivalence Discussion

Table 1: Substantial equivalence comparison

Items	Proposed device	Predicate device	Comments
Trade name	Aidite Pmma	PMMA Block	/
510(K) submitter	Aidite (Qinhuangdao) Technology Co., Ltd.	Rizhao Huge Dental Industry Co., Ltd	/
510(K) number	K190217	K141421	/
Classification	21 CFR 872.3770	21 CFR 872.3770	Same

regulation	Temporary crown and bridge resin	Temporary crown and bridge resin	
Classification and product code	II EBG	II EBG	Same
Indication for use	The device is made from PMMA (polymethylmethacrylate) for the fabrication of temporary crowns and bridges and is intended for use in the oral cavity for up to six (6) months while awaiting a permanent restoration. Restorations are designed and manufactured by a dental Professional (Technician) using CAD technology.	A device made from PMMA (polymethylmethacrylate) for the fabrication of temporary crowns and bridges and is intended for use in the oral cavity for up to six (6) months while awaiting a permanent restoration. Restorations are designed and manufactured by a dental Professional (Technician) using CAD technology.	Same
Material of construction	PMMA	PMMA	Same
Shades	17 Shades (Transparent, 16 Vita Shades)	20 Vita Shades	Different Issue 1
Processing method	Variable Thickness Milling Blank and machined using any milling system	Variable Thickness Milling Blank and machined using any milling system	Same
Flexural strength	≥50 MPa	≥50 MPa	Same
Shelf life	2 years	5 years	Different Issue 2
Performance effectiveness	Tested according to ISO 10477	Tested according to ISO 10477	Same
Performance safety	Tested according to ISO 10993 standards	Tested according to ISO 10993 standards	Same

Issue 1: The transparent shade is made from PMMA without color added. The 16 Vita shades are designed in accordance with VITA classical A1-D4. The shade consistency, color stability and the biocompatibility of Aidite Pmma has been evaluated by conducting tests.

Issue 2: The 2-year shelf life of the proposed device has been proved by conducting accelerated aging test.

8. Non-Clinical Performance Data

1) Biocompatibility test

The Aidite Pmma is classified as surface-contacting device. For duration of contact, the Aidite Pmma is considered as permanent contact devices. In accordance with ISO 10993-1 and ISO 7405, the biocompatibility tests contain:
ISO 7405: 2008 & ISO 10993-5: 2009 Agar diffusion test
ISO 7405: 2008 & ISO 10993-5: 2009 Filter diffusion test
ISO 10993-5: 2009 In Vitro cytotoxicity test
ISO 10993-10: 2010 Skin sensitization test
ISO 10993-10: 2010 Oral mucosa irritation test
ISO 10993-11: 2017 Subchronic systemic toxicity
ISO 10993-3: 2014 Genotoxicity

2) Shelf life validation test

The shelf life validation test of the proposed devices was conducted after accelerated aging for 2 years (ASTM F 1980):

3) Performance test-bench

The performance of Aidite Pmma contains surface finish, flexural strength, bond strength, water sorption and solubility, shade consistency and color stability. All the results meet the acceptance criteria, they also demonstrate that the Aidite Pmma meet the performance characteristics and are substantially equivalent to the legally marketed predicate devices. The performance tests were conducted in accordance with the following standards:
ISO 10477: 2018 Dentistry-Polymer-based crown and bridge materials;
ISO 7491: 2000 Dental materials-Determination of color stability.

9. Statement of Substantial Equivalence

The Indications for Use and technological characteristics for Aidite Pmma are same to the referenced predicate devices (K141421). The non-clinical performance testing demonstrates that the proposed device is substantially equivalent to the predicate devices. Therefore, the results show that it is Substantially Equivalent (SE) between the proposed device and the predicate device.