February 16, 2023

Aidite (Qinhuangdao) Technology Co., Ltd.
% Boyle Wang
Official Correspondent
Shanghai Truthful Information Technology Co., Ltd.
RM.1801 ,No.161, East Lu Jiazui Rd., Pudong
Shanghai, Shanghai 200120
CHINA

Re: K223477
Trade/Device Name: PMMA Blocks for Dental Use
Regulation Number: 21 CFR 872.3770
Regulation Name: Temporary Crown And Bridge Resin
Regulatory Class: Class II
Product Code: EBG
Dated: November 15, 2022
Received: November 18, 2022

Dear Boyle Wang:

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,
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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)*
K223477

Device Name
PMMA Blocks for Dental Use

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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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**K223477**

# 510(k) Summary

This summary is submitted in accordance with 21 CFR 807.92.

## 1.0 Submission Sponsor

Name: Aidite (Qinhuangdao) Technology Co., Ltd.
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## Designated Submission Correspondent

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Date of Preparation: Nov.15,2022

## 2.0 Device Information

Trade name: PMMA Blocks for Dental Use
Device name: Aidite Pmma
Common name: Crown And Bridge, Temporary, Resin
Classification name: Temporary crown and bridge resin
Production code: EBG
Regulation number: 21 CFR 872.3770
Classification: Class II
Panel: Dental

## 3.0 Identification of Predicate Device and Reference Device

510(k) Number: K190217 (Primary Predicate)
Product Name: Aidite Pmma
Manufacturer: Aidite (Qinhuangdao) Technology Co., Ltd.

This predicate has not been subject to a design-related recall.

## 4.0 Device Description

The PMMA Blocks for Dental Use 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 39 specifications for Cylinder model (variation in different diameters and heights), and 44 specifications for Cuboid model (variation in different lengths, widths, and heights).

There are 20 various shades of the proposed device: 1 is transparent (without color added), the other 19 shades are colored (with different coloring matters added). The 19 shades created based on 19 Vita Shades contain A1, A2, A3, A3.5, A4, B1, B2, B3, B4, C1, C2, C3, C4, D2, D3, D4 and OM1,OM2,OM3.

The PMMA Blocks for Dental Use would be produced on the 39 specifications of Cylinder model or 44 specifications of Cuboid model, with a shade chosen from the 20 various shades.

The PMMA Blocks for Dental Use is provided as non-sterile.

## 5.0 Indication 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.

## 6.0 Summary of Non-Clinical Testing

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

ISO 10477: 2018 Dentistry-Polymer-based crown and bridge materials;
ISO 7491: 2000 Dental materials-Determination of color stability.

**Shelf Life Validation Test**

The shelf life validation test of the proposed devices was conducted after accelerated aging for 5 years (ASTM F 1980)

**Biocompatibility Testing:**

Biocompatibility testing per following standards is performed to verify the equivalent safety of the materials that are used:

ISO 10993-5: 2009 Biological evaluation of medical devices-Part 5: tests for in vitro cytotoxicity
ISO 10993-10 :2010 Biological evaluation of medical devices –Part 10:Tests for irritation and skin sensitization
ISO 10993-11:2017, Biological evaluation of medical devices - Part 11: Tests for systemic toxicity.
ISO 10993-6 :2016, Biological evaluation of medical devices -- Part 6: Tests for local effects after implantation
ISO 10993-3 Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity.

## 7.0 Summary of Clinical Test

Clinical testing was not required for this submission.

## 9.0 Technological Characteristics and Substantial Equivalence

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

Table1 General Device Characteristics Comparison Table

| Item | Subject Device | Predicate device | Remark |
|---|---|---|---|
| 510(k) No. | Pending | K190217 | |
| Product Name | PMMA Blocks for Dental Use | Aidite Pmma | -- |
| Product Code | EBG | EBG | Same |
| Regulation No. | 21 CFR 872.3770 | 21 CFR 872.3770 | Same |
| Class | II | II | Same |
| Intended 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. | 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. | Same |
| Prescription Use | Yes | Yes | Same |
| Shapes | 20 Shades<br>(1 Transparent, 19 Vita Shades) | 17 Shades<br>(1 Transparent, 16 Vita Shades) | Similar |
| Material of construction | PMMA+ Pigments, | PMMA+ Pigments, Cross-linking agent, Curing agent, | Analysis 1 |
| Processing method | 1)Dilute the color material and PMMA powder;<br>2)Mix the diluent and PMMA powder<br>3)Powder subpackage<br>4)Hot pressing<br>5)Cooling pressure molding<br>6)Post-curing reaction | 1)Pre-polymerization<br>2)Add prepared coloring matter based on the required shade;<br>3)Low-temperature polymerization<br>4)High-temperature polymerization<br>5)Cutting | Analysis 2 |
| Specification | Various | Various | Same |
| Shelf life | 5 years | 2 years | Analysis 3 |
| Sterile | Non-sterile | Non-sterile | Same |

| | | | |
|---|---|---|---|
| Performance Test | Tested according to ISO 10477 | Tested according to ISO 10477 | Same |
| Biocompatibility | Comply with ISO 10993-1:2018, FDA Guidance, tests included cytotoxicity, oral mucosa irritation, skin sensitization, Subchronic systemic toxicity, genotoxicity, Acute Systemic Toxicity and Pyrogens. | Tested according to ISO 10993 standards. | Same |

Analysis:

The subject device is highly similar to the predicate device in terms of indications for use, design and main material.
The subject device is different from the predicate device in the following:

1) Material/Chemical Composition - The Subject and Predicate devices are same highly similar in they are both methacrylate polymer resins. Slight differences in chemical composition do not change the intended use of the Subject and Predicate devices to be used in the fabrication of temporary dental prostheses. The materials are an alternative to traditional heat cured and auto polymerization resins. The Subject device has demonstrated suitability for intended use through material non-clinical performance testing.

2) Processing method-The subject device has different processing with the predicate device. Performance testing has been performed per ISO 10477.The test results shown the subject device is fully complied with the requirements of the above standard. So the subject device is substantially equivalent to the predicate device.

3) Shelf life of the Subject device is different with that of the predicate device. The shelf life validation test of the proposed devices was conducted after accelerated aging for 5 years. The difference will have no effect on the substantial equivalence.

In summary, the main components of the subject device and its predicate are substantially equivalent, and the slight differences does not affect the substantial equivalence of the subject device when compared to the predicate device.

## 10.0 Conclusion

The conclusions drawn from the comparison and analysis above demonstrate that the differences between the subject device and the predicate device are insignificant in terms of substantial equivalence. The proposed device is substantially equivalent to the predicate device.