March 17, 2023

Aidite (Qinhuangdao) Technology Co., Ltd
% Julie Chen
Consultant
ICAS Group
155 Pingbei Rd, Minghang
Shanghai, Shanghai 201100
CHINA

Re: K230115
Trade/Device Name: Denture Base Resin
Regulation Number: 21 CFR 872.3760
Regulation Name: Denture Relining, Repairing, Or Rebasing Resin
Regulatory Class: Class II
Product Code: EBI
Dated: January 13, 2023
Received: January 17, 2023

Dear Julie Chen:

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,
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)*
K230115

Device Name

Denture Base Resin

Indications for Use *(Describe)*

Denture Base Resin is used for the fabrication of removable dentures.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

510(K) Summary
K230115

I. SUBMITTER:

Aidite (Qinhuangdao) Technology Co., Ltd
No.9 Dushan Road, Economic and
Technological Development
Zone,Qinhuangdao City China
Contact Person: Chen Yingying
Title: Registered Engineer
Tel: 15033560085
Email: chenyingying@aidite.com

Submission Correspondent： Julie Chen
Email: cl.julie@hotmail.com
Tel:+86 139 1804 5781

Summary prepared：03/16/2023

II. DEVICE

Name of Device: Denture Base Resin
Trade Name: Denture Base Resin
Common Name: Denture Relining, Repairing, or Rebasing Resin
Regulation Number: 21 CFR PART 872.3690
Classification Name: Denture Relining, Repairing, or Rebasing Resin
Regulatory Class: II
Product Code: EBI

III. PREDICATE DEVICE

Primary predicate device: K151142(IvoBase CAD for Zenotec, IvoBase CAD Bond, and Modelling Liquid)

IV. DEVICE DESCRIPTION

The Denture Base Resin mainly consist of denture base resin (powder), polymethyl methacrylate (PMMA), methyl methacrylate, ethylene glycol dimethacrylate, titanium dioxide, ferric oxide, iron oxide yellow and ferric tetroxide. The resin block is milled using the CAD/CAM technique to form the removable dentures. The product combines the prosthetic denture teeth with the denture base.

V. AVAIABLE MODEL

Model	Shade	Specification
FDB-LC	A1P1、A2P1、A3P1、A3.5P1、A4P1、B1P1、B2P1、C1P1、C2P1、OM1P1、BL3P1、A1P2、A2P2、A3P2、A3.5P2、A4P2、B1P2、B2P2、C1P2、C2P2、OM1P2、BL3P2、A1P3、A2P3、A3P3、A3.5P3、A4P3、B1P3、B2P3、C1P3、C2P3、OM1P3、BL3P3、A1P4、A2P4、A3P4、A3.5P4、A4P4、B1P4、B2P4、C1P4、C2P4、OM1P4、BL3P4、A1P5、A2P5、A3P5、A3.5P5、A4P5、B1P5、B2P5、C1P5、C2P5、OM1P5、BL3P5、A1P6、A2P6、A3P6、A3.5P6、A4P6、B1P6、B2P6、C1P6、C2P6、OM1P6、BL3P6	Disc shape：95×20、95×25、95×30、95×35、95×38、95×40、98×20、98×25、98×30、98×35、98×38、98×40（Unit: mm） Horseshoe：101×20、101×25、101×30、101×35、101×38、101×40（Unit: mm）
	B3P2、B3P4、B3P5、B4P2、B4P4、B4P5、C3P2、C3P4、C3P5、C4P2、C4P4、C4P5、D2P2、D2P4、D2P5、D3P2、D3P4、D3P5、D4P2、D4P4、D4P5、OM2P2、OM2P4、OM2P5、OM3P2、OM3P4、OM3P5、BL1P2、BL1P4、BL1P5、BL2P2、BL2P4、BL2P5、BL4P2、BL4P4、BL4P5	Disc shape：98×30、98×35、98×38（Unit: mm）
FDB-LM	A1P1、A2P1、A3P1、A3.5P1、A4P1、B1P1、B2P1、C1P1、C2P1、OM1P1、BL3P1、A1P2、A2P2、A3P2、A3.5P2、A4P2、B1P2、B2P2、C1P2、C2P2、OM1P2、BL3P2、A1P3、A2P3、A3P3、A3.5P3、A4P3、B1P3、	Disc shape：95×20、95×25、95×30、95×35、95×38、95×40、98×20、98×25、98×30、98×35、98×38、98×40（Unit: mm） Horseshoe：101×20、101×25、101×30、101×35、101×38、

	B2P3、C1P3、C2P3、OM1P3、BL3P3、A1P4、A2P4、A3P4、A3.5P4、A4P4、B1P4、B2P4、C1P4、C2P4、OM1P4、BL3P4、A1P5、A2P5、A3P5、A3.5P5、A4P5、B1P5、B2P5、C1P5、C2P5、OM1P5、BL3P5、A1P6、A2P6、A3P6、A3.5P6、A4P6、B1P6、B2P6、C1P6、C2P6、OM1P6、BL3P6	101×40（Unit: mm）
	B3P2、B3P4、B3P5、B4P2、B4P4、B4P5、C3P2、C3P4、C3P5、C4P2、C4P4、C4P5、D2P2、D2P4、D2P5、D3P2、D3P4、D3P5、D4P2、D4P4、D4P5、OM2P2、OM2P4、OM2P5、OM3P2、OM3P4、OM3P5、BL1P2、BL1P4、BL1P5、BL2P2、BL2P4、BL2P5、BL4P2、BL4P4、BL4P5	Disc shape：98×30、98×35、98×38（Unit: mm）
FDB-CC	A1P1、A2P1、A3P1、A3.5P1、A4P1、B1P1、B2P1、C1P1、C2P1、OM1P1、BL3P1、A1P2、A2P2、A3P2、A3.5P2、A4P2、B1P2、B2P2、C1P2、C2P2、OM1P2、BL3P2、A1P3、A2P3、A3P3、A3.5P3、A4P3、B1P3、B2P3、C1P3、C2P3、OM1P3、BL3P3、A1P4、A2P4、A3P4、A3.5P4、A4P4、B1P4、B2P4、C1P4、C2P4、OM1P4、BL3P4、A1P5、A2P5、A3P5、A3.5P5、A4P5、B1P5、B2P5、C1P5、C2P5、OM1P5、BL3P5、A1P6、A2P6、A3P6、A3.5P6、A4P6、B1P6、B2P6、C1P6、C2P6、OM1P6、BL3P6	Notched Disc：98×20、98×25、98×30、98×35、98×38、98×40（Unit: mm）
	B3P2、B3P4、B3P5、B4P2、B4P4、B4P5、C3P2、C3P4、C3P5、C4P2、C4P4、C4P5、D2P2、D2P4、D2P5、D3P2、D3P4、D3P5、D4P2、D4P4、D4P5、OM2P2、OM2P4、OM2P5、OM3P2、OM3P4、OM3P5、BL1P2、BL1P4、BL1P5、BL2P2、BL2P4、BL2P5、BL4P2、BL4P4、BL4P5	Notched Disc：98×30、98×35、98×38（Unit: mm）
FDB-CM	A1P1、A2P1、A3P1、A3.5P1、A4P1、	Notched Disc：98×20、98×25、

	B1P1、B2P1、C1P1、C2P1、OM1P1、BL3P1 、 A1P2 、 A2P2 、 A3P2 、A3.5P2、A4P2、B1P2、B2P2、C1P2、C2P2、 OM1P2、 BL3P2、 A1P3、A2P3、A3P3、A3.5P3、A4P3、B1P3、B2P3 、 C1P3 、 C2P3 、 OM1P3 、BL3P3 、 A1P4 、 A2P4 、 A3P4 、A3.5P4、A4P4、B1P4、B2P4、C1P4、C2P4、 OM1P4、 BL3P4、 A1P5、A2P5、A3P5、A3.5P5、A4P5、B1P5、B2P5 、 C1P5 、 C2P5 、 OM1P5 、BL3P5 、 A1P6 、 A2P6 、 A3P6 、A3.5P6、A4P6、B1P6、B2P6、C1P6、C2P6、 OM1P6、 BL3P6	98×30、98×35、98×38、98×40（Unit: mm）
	B3P2、B3P4、B3P5、B4P2、B4P4、B4P5、C3P2、C3P4、C3P5、C4P2、C4P4、C4P5、D2P2、D2P4、D2P5、D3P2、D3P4、D3P5、D4P2、D4P4、D4P5、OM2P2、OM2P4、OM2P5、OM3P2、OM3P4、OM3P5、BL1P2、BL1P4、BL1P5、BL2P2、BL2P4、BL2P5、BL4P2、BL4P4、BL4P5	Notched Disc：98×30、98×35、98×38（Unit: mm）
FDB-C	P1、P2、P3、P4、P5、P6	Disc shape：98×20、98×22、98×25、98×28、98×30、98×35、98×38、98×40、95×20、95×22、95×25、95×28、95×30、95×35、95×38、95×40（Unit: mm） Horseshoe：101×20、101×22、101×25、101×28、101×30、101×35 、 101×38 、 101×40（Unit: mm）

VI. INTENED USE per 21CFR 807.92(A)(5)

Denture Base Resin is used for the fabrication of removable dentures.

VII. INDICATIONS for USE per Form FDA 3881

Denture Base Resin is used for the fabrication of removable dentures.

VIII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Denture Base Resin are compared with the predicate device, IvoBase CAD for Zenotec and IvoBase CAD Bond and Modelling Liquid (K151142). The results are shown below in the Technological Characteristics Comparison Table:

Item	**Subject Device** Denture Base Resin	**Predicate Device** IvoBase CAD for Zenotec and IvoBase CAD Bond and Modelling Liquid	**Remark**
510(k) number	K230115	K151142	--
Regulation Number	21 CFR PART 872.3690	21 CFR PART 872.3690	SE
Product Code	EBI	EBI	SE
Common name	Denture Relining, Repairing, or Rebasing Resin	Denture Relining, Repairing, or Rebasing Resin	SE
Classification	II	II	SE
Manufacturer	Aidite (Qinhuangdao) Technology Co., Ltd	Ivoclar Vivadent, Incorporated	--
Intended Use	Denture Base Resin is used for the fabrication of removable dentures.	IvoBase CAD for Zenotec, IvoBase CAD Bond and Modelling Liquid is a system used: For the fabrication of removable dentures,e.g.: • partial and complete denture prosthetics • hybrid denture prosthetics • combined denture prosthetics • mouthguards • implant-supported denture prosthetics	SE

Type Use	Prescription (Rx Only)	Prescription (Rx Only)	SE
CAD CAM Technology	Denture Base Resin is intended for use in the fabrication of denture prosthetics using CAD CAM Technology.	IvoBase CAD for Zenotec is a PMMA disc intended for use in the fabrication of denture prosthetics using CAD CAM Technology.	SE
Monomer/polymer form	The resin block is formed using CAD CAM technology. The product combines the prosthetic denture teeth with the denture base.	The denture base is formed using CAD CAM technology. The prosthetic denture teeth are then bonded to the denture base using IvoBase CAD Bond and IvoBase CAD Modelling Liquid. IvoBase CAD Bond consists of a powder polymer and monomer liquid similar to a traditional denture base device.	Similar
Principle of operation	**Step-by-step:** • Design and processing of CAD/CAM removable dentures • Separate After CAD/CAM cutting, the restoration is separated from the resin block with a tungsten carbide or diamond bur. • Polishing • Cleaning and disinfection • - Insertion	**Step-by-step:** • - Anatomical impression and pre- bite registration • - Lab makes scan of impression and mills individual tray • - Functional impression and bite registration • - Lab makes scan and mills try-in body (Tray Disc for Zenotec) • - Try-in and esthetic, functional check • - Lab makes final denture. IvoBase CAD for Zenotec can be processed using the Zenotec select milling machine. First the lingual side is milled, then the teeth are bonded in position using ivoBase CAD Bond and then the basal side is milled. • - After milling, the denture base is separated from the disc, shape	SE

		adjustments are made and then it is polished. • - Insertion	
Composition	The Denture Base Resin mainly consist of denture base resin (powder), polymethyl methacrylate (PMMA), methyl methacrylate, ethylene glycol dimethacrylate, titanium dioxide, ferric oxide, iron oxide yellow and ferric tetroxide.	The chemical composition of the new product and predicate are the same, except for small changes in pigments and the fact that the disc product is industrially polymerized. Therefore certain ingredients (the methyl methacrylate and initiators) are no longer present. The result of the biocompatibility assessment is that the product is equivalent to the predicate.	Similar
Biocompatibility	Biocompatibility in accordance to 10993-1(Surface device in contact with mucosal membrane with permanent contact (>30 d))	Biocompatibility in accordance to 10993-1(Surface device in contact with mucosal membrane with permanent contact (>30 d))	Same
Performance	Ultimate flexural strength 87 Mpa; Flexural modulus 2340Mpa; Residual methyl methacrylate monomer 1.29% Sorption 23.64 μg/mm^3 Solubility 0.25 μg/mm^3 Maximum stress intensity factor for materials with improved impact resistance 2.89MPa m$^{1/2}$ Total fracture work 1609 J/m^2	Ultimate flexural strength82 Mpa; Flexural modulus 2032Mpa; Residual methyl methacrylate monomer1.34% Sorption 19.48 μg/mm^3 Solubility 0.65 μg/mm^3 Maximum stress intensity factor for materials with improved impact resistance 2.35 MPa m$^{1/2}$ Total fracture work 1411 J/m^2	Similar

IX. SUBSTANTIAL EQUIVALENCE DISCUSSION per 21 CFR 807.92(b)

Denture Base Resin has been conducted biocompatibility studies in accordance with ISO 10993 to demonstrate the device is as safe as its predicate device. The performance bench testing was conducted to demonstrate that the subject device is as effective as its predicate device.

X. PERFORMANCE DATA

Non-Clinical Performance Test Conclusion

Biocompatibility

Based on Table A.1 of ISO 10993-1 and Table A.1 of FDA Guidance "Use of

International Standard ISO 10993-1, Biological evaluation of medical devices – Part 1_Evaluation and testing within a risk management process", the subject device is categorized as a surface device in contact with Surface device in contact with mucosal membrane with permanent contact (>30 d). The subject device was evaluated for:
Cytotoxicity
Sensitization
Irritation
Acute systemic toxicity
Subchronic systemic toxicity
Implantation
Material-mediated pyrogenicity
Genotoxicity

Performance Bench Testing

Performance testing were conducted to verify that the subject device met all design specifications was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the Dental Base Resin complies with the following standards:

- ISO20795-1: 2013 Dentistry—Base polymers —Part 1:Denture base polymers
- ISO 4049: 2019 Dentistry - Polymer-based restorative materials;
- ISO 7491: 2000 Dental materials-Determination of color stability.

The subject device and predicate device were evaluated for:
1)Surface characteristics;
2)Shape capability;
3)Colour;
4)Colour stability;
5)Translucency;
6)Freedom from porosity;
7)Ultimate flexural strength;
8)Flexural modulus;
9)Bonding to synthetic polymer teeth
10)Residual methyl methacrylate monomer
11)Sorption and solubility
12）Maximum stress intensity factor for materials with improved impact resistance and total fracture work

Clinical Test Conclusion

No clinical study is included in this submission.

XI. CONCLUSION

The conclusions drawn from the nonclinical tests demonstrate that the subject device is as safe, as effective, and performs as well as or better than the legally marketed predicate device IvoBase CAD for Zenotec and IvoBase CAD Bond and Modelling Liquid (K151142).