November 22, 2024

Aidite (Qinhuangdao) Technology Co., Ltd.
℅ Boyle Wang
General Manager
Shanghai Truthful Information Technology Co., Ltd.
Room 1801, No. 161 East Lu Jiazui Rd.,
Pudong, 200120
CHINA

Re: K242884
Trade/Device Name: Additively Manufactured Denture Resin
Regulation Number: 21 CFR 872.3760
Regulation Name: Denture Relining, Repairing, Or Rebasing Resin
Regulatory Class: Class II
Product Code: EBI
Dated: September 23, 2024
Received: September 23, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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, MChE, RAC, CQIA
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242884

Device Name

Additively Manufactured Denture Resin

Indications for Use *(Describe)*

Additively Manufactured Denture Resin is a light-cured resin indicated for the fabrication of all types of denture bases, for instance full and partial removable dentures.
Additively Manufactured Denture Resin is intended for continuous use in the oral environment, exclusively for professional dental work.
Additively Manufactured Denture Resin can be used in combination with a DLP 3D printers utilizing wavelengths at 385nm or 405nm. A 3D-printer is not part of the device.

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.

510(k) Summary

K242884

This summary is submitted in accordance with 21 CFR 807.92.

1.0 Submission Sponsor

Name: Aidite (Qinhuangdao) Technology Co., Ltd.
Address: No.9 Dushan Road, Economic and Technological Development Zone, Qinhuangdao City, China 066004
Contact: Ms. Liu Qianqian
Tel: +86 335 8587898
Fax: +86 335 8587198

Designated Submission Correspondent

Contact: Mr. Boyle Wang
Address: Shanghai Truthful Information Technology Co., Ltd.
Room 1801, No. 161 East Lu Jiazui Rd., Pudong Shanghai, 200120 China
Tel: +86-21-50313932
Email: info@truthful.com.cn

Date of Preparation: Nov.14,2024

2.0 Device Information

Trade name: EZPRINT™ DENTURE BASE
Common name: Additively Manufactured Denture Resin
Classification name: Denture relining, repairing, or rebasing resin.
Production code: EBI
Regulation number: 21 CFR 872.3760
Classification: Class II
Panel: Dental

3.0 Identification of Predicate Device and Reference Device

Predicate Device:

510(k) Number: K200461
Trade/Product Name: Freeprint denture
Manufacturer: Detax GmbH & Co. KG.

4.0 Device Description

Additively Manufactured Denture Resin is a light-cured one-component materials for dental professional use only and intended for the fabrication of full and partial removable dentures. This Product is a liquid photo-curable material that is polymerized, by the photo-initiator contained in the resin. For use in Digital Light Processing (DLP)-3D printers utilizing wavelengths at 385nm or 405nm. The specifications of this product are divided into 500g, 1000g, 5kg and 10kg according to the weight of the resin liquid.

5.0 Indication for Use Statement

Additively Manufactured Denture Resin is a light-cured resin indicated for the fabrication of all types of denture bases, for instance full and partial removable dentures.

Additively Manufactured Denture Resin is intended for continuous use in the oral environment, exclusively for professional dental work.

Additively Manufactured Denture Resin can be used in combination with a DLP 3D printers utilizing wavelengths at 385nm or 405nm. A 3D-printer is not part of the device.

6.0 Non-clinical Test Conclusion

Bench Testing:

- Physical and mechanical properties of the subject device were evaluated according to FDA-recognized version ISO 20795-1 Dentistry – Base polymers – Part 1: Denture base polymers, including Homogeneity, Surface Characteristics, Shape Capability, Color, Color Stability, Translucency, Freedom From Porosity, Ultimate Flexural Strength, Flexural Modulus, Total Fracture Work, Maximum Stress Intensity Factor, Surface Hardness, Bonding To Synthetic Polymer Teeth, Water Sorption, Solubility, Impact Resistance.

Performance testing confirmed the subject Additively Manufactured Denture Resin demonstrated performance to the acceptance criteria referred to ISO 20795-1 for Type 4 light - activated materials. The composition of Additively Manufactured Denture Resin exhibits sufficient strengths and performances in all intraoral conditions and will sufficiently resist compressive & tensile loads, hardness, water sorption and solubility.

- Printers Validation: Two printers are validated for processing (3D printing) using the candidate device. Additional printers post-510(k) clearance will be added to the labelling by means of the Quality Systems and within the validation plan presented in this 510(k).

Biocompatibility Testing:
The nature of body contact of materials used in the design of the Additively Manufactured Denture Resin were classified as being Surface Devices in contact with mucosal membrane with a permanent contact duration of >30 days.The biocompatibility testing was performed according to FDA currently-recognized versions of biocompatibility consensus standards ISO 10993-1:2018 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process and ISO 7405:2018 Dentistry – Evaluation of biocompatibility of medical devices used in dentistry.
The following biological safety aspects have been addressed:

- Cytotoxicity – ISO 10993-5
- Sensitization – ISO 10993-10
- Irritation or intracutaneous reactivity – ISO 10993-23
- Acute Systemic Toxicity- ISO 10993-11
- Subacute/subchronic systemic toxicity – ISO 10993-11
- Genotoxicity – ISO 10993-3

Sterility and Shelf-Life Testing:
The device is provided non-sterile.
From the Shelf life testing, Additively Manufactured Denture Resin has a shelf life of 2 years.

7.0 Summary of Technological Characteristics of the Subject Device Compared to the Predicate Device

The subject device, Additively Manufactured Denture Resin and the predicate device Freeprint denture, have the same intended use and indication.
The candidate device has the following key technological characteristics similarities to the predicate device:

- Similar type of materials that form the basis for the device
- Used Same technology, however different wavelength used for polymerization (Curing) method
- Similar mechanical and physical properties of processed device.

8.0 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.

Table 1- Comparison of Technology Characteristics

Item	Subject Device	Predicate Device	Remark
510(k) No.	K242884	K200461	
Product Name	Additively Manufactured Denture Resin	Freeprint Denture	--
Product Code	EBI	EBI	Same
Regulation No.	21 CFR 872.3760	21 CFR 872.3760	Same
Class	II	II	Same
Intended Use/ Indication for Use	Additively Manufactured Denture Resin is a light-cured resin indicated for the fabrication of all types of denture bases, for instance full and partial removable dentures. Additively Manufactured Denture Resin is intended for continuous use in the oral environment, exclusively for professional dental work. Additively Manufactured Denture Resin can be used in combination with a DLP 3D printers utilizing wavelengths at 385nm or 405nm. A 3D-printer is not part of the device.	FREEPRINT denture is a light-cured resin indicated for the fabrication of all types of denture bases, for instance full and partial removable dentures. FREEPRINT denture is intended for continuous use in the oral environment, exclusively for professional dental work. FREEPRINT denture can be used in combination with a stereolithographic 3D printer using a 385nm light source. A 3D-printer is not part of the device.	Same (Analysis 1)
Prescription Use	Yes	Yes	Same
State	Liquid	Liquid	Same
Materials	Composed of acrylic resin, photo initiator, organic pigment and inorganic pigment.	Dimethacrylate-based resins with photo-initiator, and pigments.	Similar
Materials Types and Classes	Type 4: Light-activated materials	Type 4: Light-activated materials	Same
Color	P1- dark pink, P2- red pink, P3- orange pink, P4- light pink	pink-transparent and pink	Different (Analysis 2)
Specifications	Stored in 500g,1000g,5kg,10kg HDPE bottles.	Stored in 500ml and 1000ml HDPE bottles.	Different (Analysis 3)
Ultimate flexural strength			
Flexural			

modulus	Meet the requirements of ISO 20795-1:2013	Meet the requirements of ISO 20795-1:2013	Same
Stress intensity factor			
Fracture work			
Residual monomer			
Water sorption			
Water solubility			
Sterile	Non-sterile	Non-sterile	Same
Biocompatibility	Comply with ISO 10993-1:2018, and ISO 7405:2018	Comply with ISO 10993-1, ISO 7405:2018	Same

Analysis*:

1) The subject Additively Manufactured Denture Resin and the predicate device share the same intended use and indication for use, which is the fabrication of all types of denture bases, including full and partial removable dentures. The difference between the subject and predicate devices is the type of 3D printer and the range of wavelengths used in the printing process.

   While the subject device can be used with DLP 3D printers operating in a wider range of wavelengths (385nm to 405nm), the predicate device is limited to stereolithographic printers using a 385nm light source. However, both devices are designed to utilize similar light-curing mechanisms and wavelengths that initiate the same polymerization process in the resin. These differences do not raise new questions regarding safety or effectiveness. Since both devices are designed for the same intended use, have similar technological principles, and meet the performance standards of ISO 20795-1, the differences do not affect their substantial equivalence.

2) The subject device provides a wider range of pink shades .The different color due to the composition in the content of pigments. With the increase of the pigment content of the product to reduce the degree of transmittance, that is, the depth of light transmission is reduced, so the curing depth is reduced.

   These color variations do not raise new questions of safety or effectiveness, as both devices meet the required performance and biocompatibility standards. Therefore, the differences in color do not impact the substantial equivalence of the subject device to the predicate device.

3) The specifications are divided into different volume according to the weight of the resin liquid. The composition of different specifications is the same, the production process is the same, only the filling quantity is different, and there is no differential effect on the physical and chemical properties and biocompatibility.
   Therefore, the difference in specification do not impact the substantial equivalence of the subject device to the predicate device.

10.0 Conclusion

The conclusions drawn from the comparison and analysis above demonstrate that the subject device is substantially equivalent to the legally marketed predicated device.