April 30, 2025

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

Re: K250497
Trade/Device Name: Additive Manufacturing (Light Curing) Crown Bridge Resin
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: Class II
Product Code: EBF, EBG, POW, PZY
Dated: February 20, 2025
Received: February 20, 2025

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 Adjodha, MChE, RAC, CQIA
Assistant Director
DHT1B: Division of Dental and
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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)*
K250497

Device Name
Additive Manufacturing (Light Curing) Crown Bridge Resin

Indications for Use *(Describe)*
Additive Manufacturing (Light Curing) Crown Bridge Resin is a light-cured resin indicated for the fabrication of permanent single crowns in the anterior and posterior region, denture teeth, inlays, onlays, veneers and implant crown. It is also used for long-term provisional crowns and bridges.

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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510(k) Summary

K250497

This summary is submitted in accordance with 21 CFR 807.92.

1.0 Submission Sponsor

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Date of Preparation: Apr.24,2025

2.0 Device Information

Trade name: EZPRINT™ CERAMIC CROWN
Common name: Additive Manufacturing (Light Curing) Crown Bridge Resin
Model: Monochromatic
Classification name: Material, Tooth Shade, Resin
Production code: EBF
Regulation number: 21 CFR 872.3760
Classification: Class II
Panel: Dental

3.0 Identification of Predicate Device and Reference Device

Primary Predicate Device:

510(k) Number: K222877
Trade/Product Name: Freeprint denture

Manufacturer: DETAX GmbH

Predicate Device 2:
510(k) Number: K233596
Trade/Product Name: VarseoSmile TriniQ
Manufacturer: BEGO Bremer Goldschlägerei Wilh. Herbst GmbH & Co. KG

4.0 Device Description

Additive Manufacturing (Light Curing) Crown Bridge Resin is a light-curing, hybrid dental material, composed of methacrylic acid esters, inorganic filler, photoinitiator, organic pigments, inorganic pigments and additives. It is Liquid resin for dental 3D printing of permanent single crowns in the anterior and posterior region, denture teeth, inlays, onlays, veneers and implant crown. It is also used for long-term provisional crowns and bridges. The Subject device is used by a dentist or dental technician for the CAD/CAM manufacturing of temporary or permanent dental restorations.For use in Digital Light Processing (DLP)- 3D printers utilizing wavelengths at 385nm or 405nm.

The Subject device is packaged in black plastic bottles made of high density polyethylene (HDPE) according to the weight of the resin liquid.
There are different shades A1, A2, A3, A3.5, A4, B1, B2, B3, B4, C1, C2, C3, C4, D2, D3, D4, BL1, BL2, BL3, BL4, and the different shades are reflected in the different colors of finished restorations.

5.0 Indication for Use Statement

Additive Manufacturing (Light Curing) Crown Bridge Resin is a light-cured resin indicated for the fabrication of permanent single crowns in the anterior and posterior region, denture teeth, inlays, onlays, veneers and implant crown. It is also used for long-term provisional crowns and bridges.

6.0 Non-clinical Test Conclusion

Bench Testing:
- Physical and mechanical properties of the subject device were evaluated according to FDA-recognized version ISO 4049 Dentistry - Polymer-based restorative materials and ISO 10477 Dentistry - Polymer-based crown and veneering materials.

Performance testing including Appearance, Viscosity, Density, Shade, Depth of cure, Surface finish, Vickers hardness, Flexural Strength, Water Sorption, Water Solubility, Bond strength, Shade consistency, Color stability and Accuracy.
The test results demonstrated the Subject device meets the property requirements of the referenced standards.

- 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 Additive Manufacturing (Light Curing) Crown Bridge 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 – ISO 10993-23
- Acute Systemic Toxicity- ISO 10993-11
- Subchronic Systemic Toxicity – ISO 10993-11
- Genotoxicity – ISO 10993-3
- Implantation_ISO 10993-6

Sterility and Shelf-Life Testing:
The device is provided non-sterile.
From the Shelf life testing, Additive Manufacturing (Light Curing) Crown Bridge Resin has a shelf life of 3 years.

7.0 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	Primary Predicate Device	Predicate Device 2	Remark
510(k) No.	K250497	K222877	K233596	
Product Name	Additive Manufacturing (Light Curing) Crown Bridge Resin	FREEPRINT® crown	VarseoSmile TriniQ	--
Product Code	EBF	EBF	EBF, EBG, PZY	Same
Regulation No.	21 CFR 872.3690	21 CFR 872.3690	21 CFR 872.3690	Same
Class	II	II	II	Same
Intended Use/ Indication for Use	Additive Manufacturing (Light Curing) Crown Bridge Resin is a light-cured resin indicated for the fabrication of permanent single crowns in the anterior and posterior region, denture teeth, inlays, onlays, veneers and implant crown. It is also used for long-term provisional crowns and bridges.	FREEPRINT® crown is indicated as an indirect restorative for both anterior and posterior restorations, including occlusal surfaces. The FREEPRINT® crown material is used for fabricating temporary or permanent restorations such as crowns and bridges, inlays, onlays, veneers and full crown restorations. Fabrication of FREEPRINT® crown requires a computer-aided and manufacturing (CAD/CAM) system that includes the following: scanner, design software, additive printer, and post-cure unit	VarseoSmile TriniQ is indicated as an indirect restorative for both anterior and posterior restorations, including occlusal surfaces. The VarseoSmile TriniQ material is used for fabricating permanent restorations such as inlays, onlays, veneers, full crown and bridge restorations. VarseoSmile TriniQ can also be used for the fabrication of artificial teeth and temporary crowns & bridges.	Same (Analysis 1)
Prescription Use	Yes	Yes	Yes	Same
Technology	3D liquid (light-cured) print resin for dental CAD/CAM	3D liquid (light-cured) print resin for dental CAD/CAM	3D liquid (light-cured) print resin for dental CAD/CAM	Same
Materials	Methacrylic acid esters, inorganic filler, photoinitiator, organic pigments, inorganic pigments and additives	Methacrylate polymer resin with photo initiator, and pigments	Methacrylate-based resins, dental glass filler, photo initiators and pigments	Similar
Materials Shades	A1, A2, A3, A3.5, A4, B1, B2, B3, B4, C1, C2, C3, C4, D2, D3, D4, BL1, BL2, BL3, BL4	Common VITA-shades: A1, A2, A3, B1, B3, C3, D3, BL	Common VITA-shades	Different (Analysis 2)
Shelf-Life	3 years	2 years	Not publicly available	Different (Analysis 3)

Polymerization (Curing) Method	Visible light, 385 nm or 405nm w/post curing	Visible light, 385 nm w/post curing	UV light, 385 or 405 nm w/post curing	Different (Analysis 4)
Equipment	Validated 3D-Printer and post curing devices	Validated 3D-Printer and post curing devices	Validated 3D-Printer and post curing devices	Same
Performance Testing	ISO 4049:2019 ISO 10477:2020	ISO 4049:2019 ISO 10477:2020	ISO 4049:2019 ISO 10477:2020 ISO 22112:2017	Same
Depth of Cure	The hardness of the centre of the specimen of Additive Manufacturing (Light Curing) Crown Bridge Resin shall be not less than 70% of the hardness of its surface.	Hardness of bottom surface ≥70% top surface	Not publicly available	Same
Surface Finish	A polished test specimen of Additive Manufacturing (Light Curing) Crown Bridge Resin shall have a glossy surface.	Glossy surface after polishing	Not publicly available	Same
Flexural Strength	≥ 50 MPa	≥ 100 MPa	≥ 100 MPa	Different (Analysis 5)
Water Sorption	≤ 40 μg/mm^3	≤ 40 μg/mm^3	Not publicly available	Same
Water Solubility	≤ 7.5 μg/mm^3	≤ 7.5 μg/mm^3	Not publicly available	Same
Sterile	Non-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	Comply with ISO 10993-1, ISO 7405:2018	Same

Analysis*:

1) The "Indication for Use" of Additive Manufacturing (Light Curing) Crown Bridge Resin and FREEPRINT® crown are considered substantially equivalent. Both products are intended for same uses. Additionally, both products can be used for temporary or long-term restorations, with fabrication involving CAD/CAM systems and light-curing technology, ensuring consistency in their intended clinical application.

2) The subject device provides a wider range of shades. The different color due to the composition in the content of pigments. 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 difference in shelf life between the two products does not impact their Substantial Equivalence. The shelf-life validation report of the subject device

demonstrates the stability of the products' performance over time, ensuring their reliability and safety during their respective shelf lives.

4) The subject Additive Manufacturing (Light Curing) Crown Bridge Resin and the predicate device share the same intended use and indication for use. 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) that is same with that of K233596. The predicate device is limited to 3D 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 4049:2019 and ISO 10477:2020, the differences do not affect their substantial equivalence.

5) Flexural Strength requirement between the subject device and the predicate device is different. Flexural Strength $\geqslant$ 50 MPa meets the requirement specified by ISO 10477:2020, which sets the minimum standard for dental materials in terms of flexural strength. In addition, the actual test results for the subject device show that its Flexural Strength is consistently above 100 MPa, which is in alignment with that of the predicate device, confirming that the two products are substantially equivalent in terms of their performance characteristics

8.0 Summary of Clinical Test

Clinical testing was not required for this submission.

9.0 Conclusion

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