March 14, 2025

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: K250025
Trade/Device Name: Porcelain Powder (Enamel/ Modifier,Stain/Glaze,Stain/Glaze-A,Modeling Fluid)
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: March 12, 2025
Received: March 13, 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,

Bobak Shirmohammadi -S

For Michael E. Adjodha, M.ChE., 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K250025

Device Name
Porcelain Powder (Enamel/ Modifier,Stain/Glaze,Stain/Glaze-A,Modeling Fluid)

Indications for Use *(Describe)*
Porcelain Powder can be used to make facings and veneers of customized denture crowns. It is suitable for adults over 18 years old.

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

K250025

This summary is submitted in accordance with 21 CFR 807.92.

1.0 Submission Sponsor

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Date of Preparation: Mar.12nd ,2025

2.0 Device Information

Trade name: Porcelain Powder
Common name: Dental Porcelain Powder
Classification name: Porcelain Powder For Clinical Use
Model: Enamel/ Modifier, Stain/Glaze, Stain/Glaze-A, Modeling Fluid
Production code: EIH
Regulation number: 21 CFR 872.6660
Classification: Class II
Panel: Dental

3.0 Identification of Predicate Device and Reference Device

Predicate Device:

510(k) Number: K232676
Trade/Product Name: Dental Porcelain Powder
Manufacturer: Chengdu Besmile Medical Technology Co., Ltd.

4.0 Device Description

This product includes Porcelain Powder, Stain/Glaze, Stain/Glaze-A and Modeling Fluid.
Enamel/ Modifier is Enamel porcelain, its function is to make adjusted porcelain powder gently stacked in the incisal aimed at shape, and stack from incisal to the body, covering dentin porcelain;
Stain/Glaze and Stain/Glaze-A is Enamel layer, its function is to coat with a thin layer of glaze on the surface of the finishing porcelain crown to achieve the required color and gloss of natural teeth.
Modeling Fluid: A dental ceramic powder is mixed in order to shape or model it into its required form prior to firing

5.0 Indication for Use Statement

Porcelain Powder can be used to make facings and veneers of customized denture crowns.It is suitable for adults over 18 years old.

6.0 Non-clinical Test Conclusion

Bench Testing:
- Physical and mechanical properties of the subject device were evaluated according to FDA-recognized version ISO 6872:2015/AMD 1:2018 Dentistry - Ceramic materials.

Test items include uniformity, freedom from extraneous materials, mixing and compaction performance, flexural solubility, chemical solubility, radioactivity, coefficient of thermal expansion, glass transition temperature and shade and all tests were verified to meet acceptable criteria.

Biocompatibility Testing:
The nature of body contact of materials used in the design of the Porcelain Powder 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

- Oral MucOsa Irritation – ISO 10993-23
- Acute Systemic Toxicity- ISO 10993-11
- Pyrogen Test- ISO 10993-11
- Subchronic Systemic Toxicity – ISO 10993-11
- Bacterial Reverse Mutation Test– ISO 10993-3
- TK Gene Mutation Test– ISO 10993-3

Sterility and Shelf-Life Testing:
The device is provided non-sterile.
From the shelf life testing report, the Porcelain Powder has a shelf life of 3 years.

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.

Table 1- Comparison of Technology Characteristics

Item	Subject Device	Predicate Device	Remark
510(k) No.	K250025	K232676	--
Product Name	Porcelain Powder	Dental Porcelain Powder	--
Product Code	EIH	EIH	Same
Regulation No.	21 CFR 872.6660	21 CFR 872.6660	Same
Class	II	II	Same
Intended Use/ Indication for Use	Porcelain Powder can be used to make facings and veneers of customized denture crowns. It is suitable for adults over 18 years old.	This product is indicated for use as a veneering material for fixed prosthesis in crowns, bridges.	Same (Analysis 1)
Prescription Use	Yes	Yes	Same
Device Design	This product includes Porcelain Powder, Stain/Glaze, Stain/Glaze-A and Modeling Fluid.	The product form is Porcelain Powder, Stain/Glaze and Blending liquid	Similar
Materials	This product includes Porcelain Powder, Stain/Glaze, Stain/Glaze-A and Modeling Fluid. The porcelain powder is	This product includes Porcelain Powder, Stain/Glaze and Blending liquid. The porcelain powder	Different (Analysis 2)

	composed of SiO_2 (Silicon Dioxide), Na_2CO_3 (Sodium Carbonate), Li_2CO_3 (Lithium Carbonate), H_3BO_3 (Boric Acid), K_2CO_3 (Potassium Carbonate), MgO (Magnesium Oxide), $CaCO_3$ (Calcium Carbonate), ZrO_2 (Zirconium Dioxide), $BaCO_3$ (Barium Carbonate), Al_2O_3 (Aluminum Oxide), SnO_2 (Tin Dioxide). The Modifier Model is in Powder form with basic porcelain powder; Modeling Fluid Model are in Liquid form; Stain/Glaze and Stain/Glaze-A are provided in paste forms, combining the components of Modifier and Modeling Fluid, along with various pigments, and Stain/Glaze contains an additional ingredient- NaF, compared to Stain/Glaze-A.	is composed of silica (SiO2), alumina (Al2O3), potassium oxide (K2O), sodium oxide (Na2O), boron trioxide (B2O3), calcium oxide (CaO), barium oxide (BaO), zirconia (ZrO2), zinc oxide (ZnO) , lithium oxide (Li2O), tin oxide (SnO2), magnesium oxide (MgO), Yttrium oxide (Y2O3) and terbium oxide (Tb2O3).. The blending liquid is composed of purified water, 1, 3-butanediol and diethanolamine. The Stain/Glaze is composed of the porcelain powder and the blending liquid in accordance with the mass ratio of 1:1	
Conditions of use	This product is used by trained professional dentists in legitimate and legitimate customized denture.	Made by professional technicians; This product is used by trained professional operators in legitimate and legitimate customized denture production institutions.	Same
Physicochemical Properties Per ISO 6872 Dentistry – Dental Ceramics	• Uniformity •Freedom from Extraneous Materials •Mixing & Condensation Properties (Class I Ceramics) •Physical & Chemical Properties •Flexural Strength •Linear Thermal Expansion Coefficient • Glass Transition Temperature • Chemical Solubility • Radioactivity	• Uniformity • No foreign body • Mixing & Condensation Properties (Class I Ceramics) • Physical & Chemical Properties • Flexural Strength • Linear Thermal Expansion Coefficient • Glass Transition Temperature • Chemical Solubility • Radioactivity	Same
Manufacturing material	Glass ceramics	Glass ceramics	Same

Categorization by nature of body contact	Surface-contacting medical devices Mucosal membranes	Surface-contacting medical devices Mucosal membranes	Same
Categorization by duration of contact	Long-term exposure contact time exceeds 30d	Long-term exposure contact time exceeds 30d	Same
Applicable population	It is suitable for clinical patients with denture defect or absence.	It is suitable for clinical patients with denture defect or absence.	Same
Intended site	Patient's oral cavity	Patient's oral cavity	Same
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:

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

1) The subject device and predicate device are substantially equivalent in terms of their intended use and indications for use:
   a) Both devices are intended for use as veneering materials for dental prosthetic restorations;
   b) The differences in wording between the two devices' indications for use do not reflect significant functional differences and do not introduce new questions of safety or effectiveness.
   c) The subject device's focus on facings and veneers for customized denture crowns is a subset of the broader application described for the predicate device (veneering material for crowns and bridges), there is no effect on the SE determination.

2) The main ingredients are basically the same, and the candidate product has passed the biocompatibility test, and there are no new risks. Accordingly, it was concluded that the subject device is substantially equivalent in biocompatibility to the predicate device and the reference 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.