April 9, 2026

Shandong Huge Dental Material Corporation
Zheng Maggie
Regulatory Affairs Manager
68 Shanhai Rd., Donggang District
Rizhao City, 276800
CHINA

Re: K260067
Trade/Device Name: Eternal Art Porcelain Powders
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: January 9, 2026
Received: January 9, 2026

Dear Zheng Maggie:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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
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OHT1: Office of Ophthalmic, Anesthesia,
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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.

510(k) Number *(if known)*
K260067

Device Name
Eternal Art Porcelain Powders

Indications for Use *(Describe)*
This device is indicated for use as a veneering material for fixed prosthesis in crowns and bridges. It is used for external staining and glazing in prosthetic dentistry by forming a porcelain veneer on to a ceramic substructure.

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.

K260067

510 (k) Summary

This summary of 510(k) for the subjective device equivalence information is being submitted in accordance with the requirements of 21 C.F.R. 807.92.

1. **Date Summary Prepared:** April 8, 2026

2. **Submitter Information:**

Owner's Name	Shandong Huge Dental Material Corporation
Address	No. 68 Shanhai Road, Donggang District, Rizhao City, Shandong Province, 276800, P.R. China
Telephone	0086 633 2277268
Fax	0086 633 2277298
Contact Person	Ms. Maggie Zheng
Contact Title	Regulatory Affairs Manager
E-mail	zhengxy@hugedent.com

3. **Device Name**

Trade name: Eternal Art Porcelain Powders

Common name: Porcelain Powders

Classification name: Porcelain powder for clinical use (21 CFR 872.6660)

Regulatory Class: Class II

Product Code: EIH

4. **Predicate and Reference Device Information**

Owner/Operator	Device Trade Name	510 (k) No.	Product Code	Predicate / Reference
Liaoning Upcera Co., Ltd	Upcera Glaze Paste, Glaze Powder, and Glaze Liquid	K181167	EIH	Predicate (Primary)
Chengdu Besmile Medical Technology Co., Ltd.	Dental Porcelain Powder	K232676	EIH	Reference

Owner/Operator	Device Trade Name	510 (k) No.	Product Code	Predicate / Reference
Aidite (Qinhuangdao) Technology Co., Ltd	Porcelain Powder	K250025	EIH	Reference

Note: The main reason for inclusion of the reference devices, Dental Porcelain Powder (K232676) and Porcelain Powder (K250025), is to support similarities in composition of materials to the subject device.

5. Description of Device

Eternal Art Porcelain Powders are dental veneering materials used for color staining and glazing of the surfaces of restorations such as zirconia or glass-ceramic substrates. It has 3 models: Powder, Stain/Glaze and Blending Liquid. Powder is in the form of a porcelain dry powder, Blending Liquid is a material used to mix the Powder into paste form, and the Stain/Glaze is pre-mixed paste prepared by uniformly mixing the Powder and the Blending Liquid at a certain ratio, which can help dental technicians save the mixing process, and convenient to use.

Eternal Art Porcelain Powders are classified as Type I Ceramic products that are provided as powders, pastes, or aerosols according to ISO 6872:2024 Dentistry—Ceramic materials, and designed into various specifications and shades to meet different needs. Meanwhile, the production process, processing technology, raw materials and performance of different specifications are consistent.

6. Indications for Use

This device is indicated for use as a veneering material for fixed prosthesis in crowns and bridges. It is used for external staining and glazing in prosthetic dentistry by forming a porcelain veneer on to a ceramic substructure.

7. Summary of Physical and Chemical Properties Tests

The physical properties of the subject device were determined and tested according to ISO 6872:2024 and internal standard. Bench testings were performed on the subject device and the predicate device, the test results demonstrated the substantial equivalence when compared to the predicate device.

Summary of Physical and Chemical Properties Test			
Model	Items per internal standards	Pass/fail criteria	Conclusion
Powder and Stain/Glaze	Uniformity	Meet ISO 6872	Satisfactory
	Freedom from extraneous materials	Meet ISO 6872	Satisfactory
	Radioactivity	Meet ISO 6872	Satisfactory
	Mixing properties	Meet ISO 6872	Satisfactory
	Condensation properties	Meet ISO 6872	Satisfactory
	Flexural strength	Meet ISO 6872	Satisfactory
	Chemical solubility	Meet ISO 6872	Satisfactory
	Coefficient of thermal expansion	Meet ISO 6872	Satisfactory
	Glass transition temperature	Meet ISO 6872	Satisfactory
Blending Liquid	Meet internal standard		Satisfactory

8. Technological Characteristics Comparison

All components of the subject device are based upon industry well-known chemistry. The following table shows the significant technological characteristics for the subject device and indicates the following similarities and differences with the predicate and reference devices:

Technological Characteristics	Subject device K260067	Predicate device K181167
Product Name	Eternal Art Porcelain Powders	Upcera Glaze Paste, Glaze Powder, and Glaze Liquid
Company name	Shandong Huge Dental Material Corporation	Liaoning Upcera Co., Ltd
Main Composition	The Powder is mainly composed of glass powder. The Blending Liquid is mainly composed of purified water and organic solvents.	The Powder is mainly composed of glass powder. The Blending Liquid is mainly composed of purified water and organic solvents.
Physical Form	Powder, Liquid and Paste	Powder, Liquid and Paste
Indications of Use	This device is indicated for use as a veneering material for fixed prosthesis in crowns and bridges. It is used for external staining and glazing in prosthetic dentistry	“Glaze Paste, Glaze Powder, and Glaze Liquid” are indicated for use as a veneering material for fixed prosthesis in crowns and bridges. This device is used in

Technological Characteristics	Subject device K260067	Predicate device K181167
Product Name	Eternal Art Porcelain Powders	Upcera Glaze Paste, Glaze Powder, and Glaze Liquid
Company name	Shandong Huge Dental Material Corporation	Liaoning Upcera Co., Ltd
	by forming a porcelain veneer on to a ceramic substructure.	prosthetic dentistry by forming a porcelain veneer on to a ceramic substructure.
Prescription/over-the-counter use	Prescription	Prescription
Sterility	Non-sterile	Non-sterile
Physical Properties	The subject device and predicate device have substantially equivalent physical properties as they all conform to the specifications set in ISO 6872:2024 and internal standard.	

The indications of the subject device are similar to those of 510(k) cleared predicate device. Based on the similarities in indications for use, the subject device has demonstrated substantial equivalence to the predicate device, and the minor difference in wording between the two devices does not affect the substantial equivalence .

The subject device's main components are the same as those of the predicate device, with only minor difference in composition. These minor components have a history of safe use in legally marketed reference devices. Additionally, the subject device has successfully undergone biocompatibility testing. Therefore, these differences do not raise new safety risks and do not affect the substantial equivalence.

Based on ISO 6872:2024 and internal standard, technological characteristics, physical properties, performance testing are carried to compare the subject device with predicate device. According to test results, the subject device has similar technological characteristics with the predicate device.

9. Summary of Non-clinical testing

The physical properties of the subject device were determined and tested according to ISO 6872:2024 and internal standard, and the test results demonstrated the qualification and substantial equivalence when compared to the predicate device.

Additionally, the subject device is substantially equivalent to the predicate and reference devices. The compositions of the subject device do not contain any non-conventional chemicals compared to the legally marketed predicate and reference devices.

Biocompatibility tests were performed fully following the ISO 7405 and ISO 10993 standards, including Cytotoxicity, Skin sensitization, Irritation, Acute systemic toxicity, Subchronic systemic toxicity and Genotoxicity, and test results are sufficient to prove the subject device is substantially equivalent to the predicate device.

10. Clinical Performance Data

Clinical test is not applicable.

11. Conclusions

Based on the indications for use, technological characteristics, performance testing and comparison to predicate device, the subject device has demonstrated substantial equivalence. Shandong Huge Dental Material Corporation concludes that the subject device is substantially equivalent to the predicate device described herein.