January 23, 2024

Chengdu Besmile Medical Technology Co., Ltd.
Moushan Liu
Quality Manager
No.9, Sec.2, Shengwucheng North Rd., Chengdu Tianfu
International Bio-Town, Shuangliu District
Chengdu, Sichuan 610200
China

Re: K232676
Trade/Device Name: Dental Porcelain Powder
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: September 1, 2023
Received: November 24, 2023

Dear Moushan Liu:

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.

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,

FDA 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)*
K232676

Device Name
Dental Porcelain Powder

Indications for Use *(Describe)*
This product is indicated for use as a veneering material for fixed prosthesis in crowns, 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.

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510(k) Summary -K232676

I 510(k) Submitter

Device Submitter: Chengdu Besmile Medical Technology Co., Ltd.
No.9,Sec.2, Shengwucheng North Rd., Chengdu Tianfu International Bio-Town, Shuangliu District, Chengdu, Sichuan 610200, P.R.China

Contact Person: Moushan Liu (Mr.)
Manager
Phone: +86-28-88415850
E-mail: 79802494@qq.com

II Device

Trade Name of Device:	Dental Porcelain Powder
Regulation Number:	21 CFR 872.6660
Classification Name:	Powder, Porcelain
Product Code:	EIH
Regulatory Class	II
Review Panel	Dental

III Predicate Devices

510k Number	**K060441, K052710**
Trade Name of Device:	Vita VM®
Regulation Number:	21 CFR 872.6660
Regulation Name:	Powder, Porcelain
Regulatory Class	II
Product Code:	EIH

IV Device Description

This product includes Porcelain Powder, Stain/Glaze and Blending liquid. The porcelain powder is composed of silica (SiO_2), alumina (Al_2O_3), potassium oxide (K_2O), sodium oxide (Na_2O), boron trioxide (B_2O_3), calcium oxide (CaO), barium oxide (BaO), zirconia (ZrO_2), zinc oxide (ZnO) , lithium oxide (Li_2O), tin oxide (SnO_2), magnesium oxide (MgO), Yttrium oxide (Y_2O_3) and terbium oxide (Tb_2O_3).. 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.

V Indications for use

This product is indicated for use as a veneering material for fixed prosthesis in crowns, bridges.

VI Technological Characteristics Comparison

VI-1: Comparison of Dental Porcelain Powder

Device Characteristic	Subject Device	Predicate Device (K060441, K052710)	Discussion
Trade name	Dental Porcelain Powder	Vita VM®	N/A
Product code	EIH	EIH	Identical
Regulation Number	21 CFR 872.6660	21 CFR 872.6660	Identical
Regulatory class	Class II	Class II	Identical
Manufacturer	Chengdu Besmile Medical Technology Co., Ltd.	VITA Zahnfabrik H.Rauter Gmbh & Co.KG	N/A
Materials	This product includes Porcelain Powder, Stain/Glaze and Blending liquid. The porcelain powder is composed of silica (SiO_2), alumina (Al_2O_3), potassium oxide (K_2O), sodium oxide (Na_2O), boron trioxide (B_2O_3), calcium oxide (CaO), barium oxide (BaO), zirconia (ZrO_2), zinc oxide (ZnO) , lithium oxide (Li_2O), tin oxide (SnO_2), magnesium oxide (MgO), Yttrium oxide (Y_2O_3) and terbium oxide (Tb_2O_3).. 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	SiO_2, Al_2O_3, K_2O, Na_2O, Li_2O, ZrO_2, BaO, CaO, Tb4O7, MgO, TiO_2, B_2O_3, SnO_2, Y_2O_3, ZnO.	Different Comment 1
Device design	The product form is Porcelain Powder, Stain/Glaze and Blending liquid	The product form is powder, mixed liquid	Similar Comment 2
Conditions of use	Made by professional technicians; This product is used by trained professional operators in legitimate and legitimate customized denture	Made by professional technicians; Used by professional dentists	Identical

Device Characteristic	Subject Device	Predicate Device (K060441, K052710)	Discussion
	production institutions.		
Physicochemical properties	Uniformity: Porcelain Powder:After mixing with the blending liquid, there should be no pigment separation. Stain/Glaze:After stirring evenly, there should be no pigment separation. No foreign body : Porcelain Powder, Stain/Glaze and Blending liquid should be free of foreign bodies. Mixing and compacting properties : Porcelain powder mixed with the blending liquid, should not agglomerate or clumps.The blended paste, after being compacted by layers, should not crack or wrinkle during the drying process. Radioactivity: Porcelain Powder and Stain/Glaze: The active concentration of uranium-238 should be≤1.0 $Bq \cdot g^{-1}$. Coefficient of linear expansion: Porcelain Powder , Stain/Glaze: should be $(10.3\pm0.5)\times10^{-6}\ K^{-1}$. Flexural strength: Porcelain Powder , Stain/Glaze: should be ≥50 MPa. Glass transition temperature: Porcelain Powder , Stain/Glaze: should be (588±20)℃. Chemical solubility: Porcelain Powder , Stain/Glaze: should be < 100 $\mu g \cdot cm^{-2}$.	Thermal expansion coefficient (25-500℃) - dentin porcelain: $(8.8\text{-}9.2)\times10^{-6}K^{-1}$ Three point bending strength - dentine porcelain: about 100MPa Conversion temperature: about 600℃ Softening point: about 670℃ Chemical solubility: $10\mu g \cdot cm^{-2}$ Average particle size - Essence porcelain: approx.$18\ \mu m(d_{50})$	Similar Comment 3

Device Characteristic	Subject Device	Predicate Device (K060441, K052710)	Discussion
	Bonding strength of veneer porcelain: Porcelain Powder , Stain/Glaze: should be > 20 MPa.		
Indications use	This product is indicated for use as a veneering material for fixed prosthesis in crowns, bridges.	Vita VM® porcelains are indicated for use as a veneering material for fixed prosthesis in crowns, bridges, and dental implant abutments. These devices are used in prosthetic dentistry by forming a porcelain veneer on to a ceramic or metal substructure into the shape of a dental crown.	Similar Comment 4
Working principle	(1) Prepare tools such as knife, coloring pen, palette and so on before use; (2) According to the specific situation of the patient who needs to repair, select the type, color number of suitable Porcelain Powder, Stain/Glaze material; (3) Use the blending liquid and porcelain powder to meet the operating habits, and then carry out the stacking and sintering operation according to the pre-designed shape of the restoration; (4) Polishing, thoroughly stirring the Stain/Glaze, applying the Stain/Glaze and sintering again to obtain the final all ceramic denture restoration.	The product is a material for making dentures. Firstly, the dental mold is designed and made according to the specific situation of the patient, and then the dental mold is shaped, sintered, polished, and finally glazed and sintered to complete the production of the prosthesis.	Similar Comment 5
Manufacturing material	Glass ceramics	Glass ceramics	Identical
Categorization by nature of body contact	Surface-contacting medical devices Mucosal membranes	Surface-contacting medical devices Mucosal membranes	Identical
Categorization by duration of	Long-term exposure- contact time exceeds 30 d.	Long-term exposure	Identical

Device Characteristic	Subject Device	Predicate Device (K060441, K052710)	Discussion
contact			
Applicable population	It is suitable for clinical patients with denture defect or absence.	It is suitable for clinical patients with denture defect or absence.	Identical
Intended site	Patient's oral cavity	Patient's oral cavity	Identical
Target user	This product is used by trained professional operators in legitimate and legitimate customized denture production institutions.	Professional technician	Identical
Intended use environment	This product is expected to be used in legal and formal custom denture manufacturing institutions, and has no special requirements on the environment.	Denture making facility	Identical

Comment 1

The main ingredients are basically the same, and the product has passed the biocompatibility test, and there are no new risks.

Comment 2

A stain/glaze is made by mixing a porcelain powder and a blending liquid.The Indications for Use of the two are only different in the description of the text, and the actual intended use is the same, which does not affect the safety and effectiveness of the product.

Comment 3

The linear expansion coefficient and glass transition temperature of the Subject Device are Predicate Device Within the range.

The chemical solubility, radioactivity and flexural strength of the Subject Device meet the standard ISO 6872:2015 Dentistry-Ceramic materials.

The average particle size does not affect safety and effectiveness.

In summary, this difference does not affect, essentially equivalent.

Comment 4

Our indication is covered by the comparison device indication.

Comment 5

The understanding of the product varies between manufacturers, and the Subject Device describes the working principle in more detail.

VII Summary of Non-clinical Testing (Bench)

The non-clinical testing for Dental Porcelain Powder was performed to demonstrate verification testing in conformance with the acceptance criteria of test methods and recognized consensus standards shown below.

Table VII-1: Performance testing was conducted on the subject device

<table>
<tr><th>ID#</th><th>Test</th><th>Method</th><th>Acceptance Criteria</th><th>Conclusion</th></tr>
<tr><td>1</td><td colspan="4">Physical Testing of Dental Porcelain Powder</td></tr>
<tr><td>1.1</td><td>Chemical composition of powder</td><td><table><tr><th>Ingredient</th><th>Content (%)</th></tr><tr><td>Silicon dioxide (SiO_2)</td><td>57-67</td></tr><tr><td>Aluminum oxide (Al_2O_3)</td><td>10 ~ 20</td></tr><tr><td>Potassium oxide (K_2O)</td><td>5 ~ 15</td></tr><tr><td>Sodium oxide (Na_2O)</td><td>3 ~ 10</td></tr><tr><td>Boron trioxide (B_2O_3)</td><td>3 ~ 6</td></tr><tr><td>Calcium oxide (CaO)</td><td>< 3</td></tr><tr><td>Barium oxide (BaO)</td><td>< 3</td></tr><tr><td>Zirconium dioxide (ZrO_2)</td><td>< 3</td></tr><tr><td>Zinc oxide (ZnO)</td><td>< 3</td></tr><tr><td>Other oxides</td><td>< 2</td></tr></table></td><td>Product technical requirements</td><td>Pass</td></tr>
<tr><td>1.2</td><td>Uniformity</td><td>Porcelain Powder:After mixing with the blending liquid, there should be no pigment separation;
Stain/Glaze: After stirring evenly,there should be no pigment separation.</td><td>Product technical requirements</td><td>Pass</td></tr>
</table>

1.3	Specification	Porcelain Powder: (20g, 50g, 100g) ±0.5g/ bottle; Stain/Glaze: (2g, 4g, 6g, 8g, 10g, 20g, 50g, 100g)±0.5g/ bottle.	Product technical requirements	Pass
1.4	No foreign body	Porcelain Powder, Stain/Glaze, Blending liquid should not be visible foreign bodies.	Product technical requirements	Pass
1.5	Radioactivity	Porcelain Powder and Stain/Glaze: the active concentration of uranium-238 should be ≤1.0 $Bq \cdot g^{-1}$	Product technical requirements	Pass
1.6	Mixing and compacting properties	When the porcelain powder is mixed with the blending liquid, it should not be caked or clumped. The blended paste, after being compacted layer by layer, should not crack or wrinkle during the drying process.	Product technical requirements	Pass
1.7	Flexural strength	Porcelain Powder , Stain/Glaze: should be ≥50 MPa.	Product technical requirements	Pass
1.8	Chemical solubility	Porcelain Powder , Stain/Glaze: should be <100 $ug \cdot cm^{-2}$.	Product technical requirements	Pass
1.9	Linear expansion coefficient	Porcelain Powder , Stain/Glaze: should be (10.3±0.5) $\times 10^{-6} K^{-1}$.	Product technical requirements	Pass
1.10	Glass transition temperatures	Porcelain Powder , Stain/Glaze: should be (588±20)℃.	Product technical requirements	Pass
1.11	Bonding strength of veneer porcelain	Porcelain Powder , Stain/Glaze: should be >20 MPa.	Product technical requirements	Pass
1.12	Blending liquid appearance	There should be no visible foreign body.	Product technical requirements	Pass
1.13	Blending liquid specification	It should be ±1 mL	Product technical requirements	Pass
2	**Biocompatibility Testing**			
2.1	Cytotoxicity	ISO 10993-5:2009	Non-cytotoxic	Pass

2.2	Delayed hypersensitivity	ISO 10993-10:2010	Non-Delayed hypersensitivity	Pass
2.3	Intradermal reaction	ISO 10993-10:2010	Non-Intradermal reaction	Pass
2.4	Acute systemic toxicity	ISO 10993-11:2017	Non-Acute systemic toxicity	Pass
2.5	Subchronic systemic toxicity	ISO 10993-11:2017	Non-Acute systemic toxicity	Pass
2.6	Genotoxicity	ISO 10993-3:2014	Non-genotoxicity	Pass

VIII Clinical Test Conclusion

No clinical study is included in this submission.

IX Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the Dental porcelain powder is as safe and effective as the predicate device.