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: K232673
Trade/Device Name: Dental Glass Ceramics
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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232673

Device Name
Dental Glass Ceramics

Indications for Use *(Describe)*
Dental Glass Ceramics are indicated for fabricating all-ceramic restorations such as veneers, inlay/ onlay, partial crowns, anterior crowns, posterior crowns, using the hot press technique or CAD/CAM system.

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 – K232673

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
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E-mail: 79802494@qq.com

II Device

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

III Predicate Devices

510k Number	**K141727**
Trade Name of Device:	Dental lithium disilicate glass ceramic block (up. Press series and up. Cad series)
Regulation Number:	21 CFR 872.6660
Classification Name:	Powder, Porcelain
Regulatory Class	II
Product Code:	EIH

IV Device Description

This product is composed of SiO_2 , Al_2O_3 , Li_2O , K_2O , Na_2O , CeO_2 , Pr_6O_{11} , ZrO_2 , P_2O_5 , CaO , MnO_2 , Er_2O_3 .

V Indications for use

Dental Glass Ceramics are indicated for fabricating all-ceramic restorations such as veneers, inlay/ onlay, partial crowns, anterior crowns, posterior crowns, using the hot press technique or CAD/CAM system.

VI Technological Characteristics Comparison

VI-1: Comparison of Dental Glass Ceramics

Device Characteristic	Subject Device	Predicate Device (K141727)	Discussion
Trade name	Dental Glass Ceramics	Dental lithium disilicate glass ceramic block (up. Press series and up. Cad series)	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.	Liaoning Upcera Co., Ltd.	N/A
Intended Use	Dental Glass Ceramics are indicated for fabricating all-ceramic restorations such as veneers, inlay/ onlay, partial crowns, anterior crowns, posterior crowns, using the hot press technique or CAD/CAM system.	Dental Lithium Disilicate Glass Ceramic Blocks (Up. Press Series and Up. CAD Series) are indicated for fabricating all-ceramic restorations such as veneers, inlay/ onlay, partial crowns, anterior crowns, posterior crowns, using the hot press technique or CAD/CAM system.	Identical
Structure Composition	SiO_2 , Al_2O_3 , Li_2O , K_2O , Na_2O , CeO_2 , Pr_6O_{11} , $Zr(Hf)O_2$, P_2O_5 , CaO , MnO_2 , Er_2O_3.	SiO_2, Li_2O, K_2O, P_2O_5, Al_2O_3, B_2O_3, and other oxides	Different Comment 1
Physical Form	Solid	Solid	Identical
Operation Principle	This product is suitable for CAD/CAM and die casting, and is suitable for various grinding and polishing equipment. (1) CAD/CAM production process: ① Digitally scan models, wax-ups or oral preparations to obtain 3D data sets; ② Software processing of 3D data sets to design restorations; ③ Computer-controlled machining tools complete the fabrication (prosthesis) process;	This product is a material for making all porcelain dentures, and the method of computer aided design/computer aided manufacturing is used to make all porcelain dentures. Use the process to obtain dental module data for scanning -CAD design denture machining model -CAD fabrication denture - denture sintering and glazing - denture finished product.	Different Comment 2

Device Characteristic	Subject Device	Predicate Device (K141727)	Discussion
	④ After 30min secondary crystallization treatment at 800℃-840℃, the finished product is made by professional technicians, and finally used by professional doctors for human denture or tooth restoration. (2) Die-casting production process: ① Use CAD/CAM computer-aided design to process wax-up restorations; ② Embed the wax-up restoration with embedding material; ③ Put the embedding ring into the muffle furnace and heat it to completely evaporate the wax-type restoration; ④ Put the embedding ring into the die-casting furnace, put it into the ceramic block for die-casting, the die-casting temperature is 930℃-960℃, and the time is 10min; ⑤ After the die-casting is cooled, use sandblasting tools to clean the embedded materials on the surface of the restoration, and then make the finished product by professional technicians, and finally use it for human dentures or tooth restoration by professional doctors. ⑥ This product is recommended to use dental casting ceramic quick embedding material, which is suitable for all die casting furnaces and sandblasting tools on the market.		

Device Characteristic	Subject Device	Predicate Device (K141727)	Discussion
Device design	The product design is cylinder and cuboid.	The product design is cylinder and cuboid.	Identical
size	Cylinder (Diameter × Height) mm： 12.5×11, 12.5×13, 12.5×15, 12.5×17, 11×8, 16×16, 98×10, 98×14, 98×18, 98×22, 95×14, 95×22, 100×12, 12×18, 20×20, 98×12, 98×16, 98×20, 98×25, 95×18, 100×10, 100×14 Cuboid (Length × Width × Height) mm： 14×12×10, 92×75×20, 15.5×13×11, 92×75×18, 18.5×14.9×12.5, 92×75×16, 18.5×16.9×12.5, 92×75×14, 18.5×17.9×12.5, 92×75×12, 72×44×42, 85×40×22, 72×42×20, 65×25×22, 72×42×18, 55×15×19, 72×42×16, 40×55×19, 72×42×14, 40×15×14, 72×42×12, 72×40×25, 93×75×16, 60×25×20, 87×56×16, 50×25×20, 75×38×16, 43×25×16, 58×29×16	Cylinder (Diameter × Height) mm： 13×10 Cuboid (Length × Width × Height) mm： 18×15×13, 40×15×15	Different Comment 3
Sterility	Non-sterile	Non-sterile	Identical
Materials	Lithium disilicate glass ceramics	Lithium disilicate glass ceramics	Identical
Physicochemical properties	Porcelain block density: ≥ 2.2g /cm^3. Flexural strength: The average flexural strength of 10 samples after sintering should be ≥300 MPa.	The density of the porcelain block can be processed :2.3 ~ 2.6g/cm^3. The density of processed porcelain after sintering :2.4 ~ 2.7g/cm^3. The biaxial bending strength of the processed porcelain block after	Different Comment 4

Device Characteristic	Subject Device	Predicate Device (K141727)	Discussion
	Chemical solubility: After final sintering should be < 100 μg/cm^2. Radioactivity: The active concentration of uranium-238 should be ≤1.0 Bq/g. Linear expansion coefficient: should be (9.7±0.5) ×10^{-6} K^{-1}. Glass transition temperature :(530±20) ℃.	sintering is greater than 300MPa. Chemical solubility of machined porcelain block after sintering: less than 100ug/cm^2. The activity of processed porcelain after sintering: the active concentration of U-238 is less than 1.0Bq/g. Coefficient of thermal expansion after sintering of machined porcelain :(8.5-11.0) ×10^{-6}K^{-1}.	
Categorization by nature of body contact	Surface-contacting medical devices Mucosal membranes	Surface-contacting medical devices Mucosal membranes	Identical
Categorization by duration of contact	Long-term exposure	Long-term exposure	Identical
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 user	The product is used by trained professional dentists in legal and formal custom denture manufacturing facilities.	It is made by professional technicians and used by professional doctors.	Identical
Clinical effect	The aesthetic restoration effect is similar to the color and appearance of natural teeth.	The aesthetic restoration effect is similar to the color and appearance of natural teeth.	Identical

Comment 1

Our Device and Predicate Device have slight differences in composition, but they all take SiO_2, Li_2O, K_2O, P_2O_5, Al_2O_3 as the main components. This does not affect the use of the product and does not create new risks.

Comment 2

The two descriptions are different, but the actual use and operation are the same. Stomatologists or dental clinic technicians use the scanning probe of a 3D dental scanner to scan models, wax patterns, or oral preparations to obtain 3D data of the patient's mouth. The scanned 3D data is analyzed and processed through the device's built-in software to obtain a 3D data model of the repaired denture. Professional technicians will then create

dentures based on three-dimensional data models for professional doctors to use for human dentures or tooth restoration.3D oral scanners are commonly used Dental medical equipment, our company only produces Dental Glass Ceramics, do not sell 3D oral scanners.

Comment 3

The size of the product is different from the predicate device, and the different size only indicates that the content size of the product does not affect the performance and intended use of the product.

Comment 4

The porcelain block density requirements of Our Device are almost the same as those of the Predicate Device, and the actual value measured by us is within the requirements of the Predicate Device. This difference does not affect product safety and efficacy.

Our Device has the similar flexural strength, chemical solubility, and radioactivity as the Predicate Device.

The linear expansion coefficient of Our Device is within the range of Predicate Device and is more accurate than Predicate Device

VII Summary of Non-clinical Testing (Bench)

The non-clinical testing for Dental Glass Ceramics 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>Test result</th><th>Conclusion</th></tr>
<tr><td>1</td><td colspan="5">Physical Testing of Dental Glass Ceramics</td></tr>
<tr><td>1.1</td><td>Material composition content</td><td><table><tr><td>Ingredient</td><td>Content (%)</td></tr><tr><td>Silicon dioxide (SiO_2)</td><td>60~75</td></tr><tr><td>Aluminum oxide (Al_2O_3)</td><td>2~7</td></tr><tr><td>Lithium oxide (Li_2O)</td><td>5~17</td></tr><tr><td>Potassium oxide + sodium oxide (K_2O+Na_2O)</td><td>1~5</td></tr><tr><td>Phosphorus</td><td>3~4</td></tr></table></td><td>Product technical requirements</td><td>Silicon dioxide (SiO_2): 68.32%
Alumina (Al_2O_3) : 4.02%
Lithium oxide (Li_2O): 13.09%
Potassium oxide + sodium oxide (K_2O+Na_2O): 3.02%
Phosphorus pentoxide(P_2O_5): 3.53%
Zirconium (hafnium)</td><td>Pass</td></tr>
</table>

		pentoxide(P_2O_5)		dioxide (Zr (Hf) O_2): 1.86% Praseodymium oxide (Pr_6O_{11}) : 1.66% Cerium dioxide (CeO_2): 1.61% Erbium oxide(Er_2O_3): 1.59% Manganese dioxide (MnO_2) : < 0.01% Calcium oxide (CaO): 0.78% Other oxides: 0.51%	
		Zirconium (hafnium) dioxide (Zr (Hf) O_2)	0.5 ~ 6		
		Praseodymium oxide (Pr_6O_{11})	≤5		
		Cerium dioxide (CeO_2)	≤2.5		
		Erbium oxide(Er_2O_3)	≤4.5		
		Manganese dioxide (MnO_2)	≤1		
		Calcium oxide (CaO)	≤1.5		
		Other oxides	≤2		
1.2	Size requirement	The deviation of specifications and dimensions shall be ± 0.5 mm.		Length: 18.47mm, 18.43mm, 18.41mm, 18.42mm, 18.48mm. Width: 14.84mm, 14.87mm, 14.82mm, 14.85mm, 14.82mm. Height: 12.36mm, 12.47mm, 12.41mm, 12.39mm, 12.38mm	Pass
1.3	Appearance	No spot cracks and foreign bodies were visible on the surface		No spotted cracks and foreign bodies were found on the surface of the sample	Pass
1.4	Porcelain block density	Should be ≥2.2g/cm^3		2.45g/cm^3	Pass
1.5	Flexural strength	The average flexural strength of 10 samples after sintering should be ≥300MPa		393.8MPa	Pass
1.6	Chemical solubility	Should the final sintering be <100ug/cm^2		29.7μg/cm^2	Pass
1.7	Radioactivity	The active concentration of uranium-238 should be ≤1.0Bq/g		<0.022Bq/g	Pass

1.8	Linear expansion coefficient	It should be (9.7±0.5) x $10^{-6}K^{-1}$		$9.4\times10^{-6}K^{-1}$	Pass
1.9	Glass transition temperature	It should be (530±20) ℃		541.3℃	Pass
2	**Biocompatibility Testing**				
2.1	Cytotoxicity	ISO 10993-5:2009	Non-cytotoxic	Pass	Pass
2.2	Delayed hypersensitivity	ISO 10993-10:2010	Non-Delayed hypersensitivity	Pass	Pass
2.3	Intradermal reaction	ISO 10993-10:2010	Non-Intradermal reaction	Pass	Pass
2.4	Acute systemic toxicity	ISO 10993-11:2017	Non-Acute systemic toxicity	Pass	Pass
2.5	Subchronic systemic toxicity	ISO 10993-11:2017	Non-Acute systemic toxicity	Pass	Pass
2.6	Genotoxicity	ISO 10993-3:2014	Non-genotoxicity	Pass	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 Glass Ceramics is as safe as effective as the predicate device.

X Warnings

It is not suitable for prostheses involving molar restoration and for prostheses involving four or more units.