March 19, 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: K232682
Trade/Device Name: Pre-Sintered Zirconia Coloring Liquid
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: December 20, 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
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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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232682

Device Name
Pre-Sintered Zirconia Coloring Liquid

Indications for Use *(Describe)*
It is only used for coloring Zirconia Dental Ceramics of our company to achieve clinical aesthetic restoration.

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.

Section 3 510(k) Summary

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.)
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II Device

Trade Name of Device:	Pre-Sintered Zirconia Coloring Liquid
Regulation Number:	21 CFR 872.6660
Classification Name:	Powder, Porcelain
Product Code:	EIH
Regulatory Class	II
Review Panel	Dental

III Predicate Devices

510k Number	K141723 (Primary predicate)
Trade Name of Device:	Upcera Coloring Liquid (I and II)
Regulation Number:	21 CFR 872.6660
Regulation Name:	Powder, Porcelain
Regulatory Class	II
Product Code:	EIH

IV Device Description

Pre-Sintered Zirconia Coloring Liquid is mainly divided into 16 colors, 26 colors and special colors.

The product is mainly composed of purified water(55%~95%), ferric chloride (0~9%), Erbium Chloride(0~17%), polyethylene glycol(2%~6%),Polydextrose(0.5%~8%),Gluconic acid(1%~2%),Citric acid(0%~1%) and Yttrium chloride(0~12%).

V Indications for use

It is only used for coloring Zirconia Dental Ceramics of our company to achieve clinical aesthetic restoration.

VI Technological Characteristics Comparison

VI-1: Comparison of Pre-Sintered Zirconia Coloring Liquid

Device Characteristic	Subject Device	Predicate Device (K141723)	Discussion
Trade name	Pre-Sintered Zirconia Coloring Liquid	Upcera Coloring Liquid (I and II)	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	It is only used for coloring Zirconia Dental Ceramics of our company to achieve clinical aesthetic restoration.	Upcera Coloring Liquid (I and II) is a liquid used for the complete or partial coloration of milled Upcera zirconia substructure and anatomy before sintering.	Similar Comment1
Structure Composition	The product is mainly composed of purified water(55%~95%), ferric chloride (0~9%), Erbium Chloride(0~17%), polyethylene glycol(2%~6%), Polydextrose(0.5%~8%),Gluconic acid(1%~2%),Citric acid(0%~1%) and Yttrium chloride(0~12%).	Water, polyethylene glycol, HCl, inorganic salts.	Similar Comment 2
Physical Form	Liquid	Liquid	Identical
Operation Principle	Immersion method: 1) Shake the coloring liquid well before dyeing. Choose the appropriate container and pour in the appropriate amount of coloring liquid. 2) Zirconia was lightly put into coloring liquid with plastic tweezers and soaked for 10 seconds. 3) Take out zirconia and dry it for	Brush or immerse zirconia dental ceramics with coloring liquid before sintering.	Similar Comment3

Device Characteristic	Subject Device	Predicate Device (K141723)	Discussion
	30-60 minutes (it is recommended to use infrared lamp or oven and place it in the position of 8-100mm under infrared lamp or at 80-90 ℃ of oven). 4) The dyed zirconia was compared with VITA*16 color system, VITA*26 color system and Special colors (O1, O2, O3, G1, G2, G3, P1, P2, P3, V1, V2, V3, TO1, TO2, TO3, TO4, BL1, BL2,BL3, BL4, 0M1, 0M2,0M3). Brushing method: 1) Shake the coloring liquid well before dyeing. Choose the appropriate container and pour in the appropriate amount of coloring liquid. 2) Zirconia was dipped in coloring liquid with a ceramic pen and brushed 1-2 times. 3) Zirconia is dried for 30-60 minutes (it is recommended to use infrared lamp or oven and place it in the position of 8-100mm under infrared lamp or at the temperature of 80-90℃ in the oven). 4) The dyed zirconia was compared with VITA*16 color system, VITA*26 color system and Special colors (O1, O2, O3, G1, G2, G3, P1, P2, P3, V1, V2, V3, TO1, TO2, TO3, TO4, BL1,		

Device Characteristic	Subject Device	Predicate Device (K141723)	Discussion
	BL2, BL3, BL4, 0M1, 0M2, 0M3).		
Bottle Size	Various	Various	Identical
Type of Packaging	Liquid container	Liquid container	Identical
Color	Various	Various	Identical
Prescription Use	Prescription only	Prescription only	Identical
Sterility	Non-sterile	Non-sterile	Identical

Comment 1

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.And both have exactly the same intended use: as a zirconia dental ceramic colorant.

Comment 2

There are some minor differences between Pre-Sintered Zirconia Coloring Liquid and the predicate device. First, the predicate device contains HCl. HCl will be evaporated with no residue left at the sintering step after the coloring liquid is applied to the zirconia dental ceramics, so it will not cause any effect to the patients. Second, Pre-Sintered Zirconia Coloring Liquid and the predicate device both use inorganic pigments(Ferric chloride and erbium chloride belong to inorganic salts).This does not raise any safety concerns as the product is tested for biocompatibility. The inorganic pigments we use also have long established safety profiles.

Comment 3

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 Pre-Sintered Zirconia Coloring Liquid 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

ID#	Test	Method	Acceptance Criteria	Conclusion
1	**Physical Testing of Pre-Sintered Zirconia Coloring Liquid**			
1.1	Specification	Specification deviation of	Product technical	Pass

	requirements	coloring liquid should be (±2 ml).	requirements	
1.2	Appearance	The coloring liquid should be homogeneous and impurity-free liquid.		Pass
1.3	Post-dyeing comparison requirements	After dyeing, there was no significant difference in color between dental specimens and VITA veneer colorimeter or standard dental specimens.		Pass
1.4	Heavy metal content	Heavy metal content (in Pb) less than 10 mg/L.		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-Subchronic 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 Pre-Sintered Zirconia Coloring Liquid is as safe as effective, and performs as well as or better than the legally marketed device.