May 20, 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
Shanghai, 200120
CHINA

Re: K250534
Trade/Device Name: Biomic Color Opaque
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: February 24, 2025
Received: February 24, 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,

MICHAEL E. ADJODHA -S

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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)*
K250534

Device Name
Biomic Color Opaque

Indications for Use *(Describe)*
Biomic Color Opaque is liquid used for coloring pre-sintered zirconia restorations. It is used for the internal surface of dental zirconia material prosthesis.

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.

K250534 - 510(k) Summary

1.0 Submission Sponsor

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Date of Preparation: May 16,2025

2.0 Device Information

Trade name: Biomic Color Opaque
Common name: Pre-Sintered Zirconia Coloring Liquid
Classification name: Porcelain Powder For Clinical Use
Product code: EIH
Regulation number: 21 CFR 872.6660
Classification: Class II
Panel: Dental

3.0 Identification of Predicate Device

510(k) Number: K232682
Trade/Product Name: Pre-Sintered Zirconia Coloring Liquid
Product code: EIH
Regulation number: 21 CFR 872.6660
Classification: Class II
Manufacturer: Chengdu Besmile Medical Technology Co., Ltd.

4.0 Device Description

Biomic Color Opaque is a liquid primarily composed of Methylacryloyl propyl trimethoxy silane, deionized water, 1, 3-butanediol, ferric chloride, citric acid, cerium nitrate, erbium nitrate, cobaltous nitrate, manganous acetate, and aluminum nitrate.
This product is designed for use on the internal surface of dental zirconia material prostheses. It penetrates tightly with the zirconia surface, forming an extremely thin shade layer that reduces the internal surface permeability of the zirconia material prosthesis. The devices are intended to be used solely by dental technicians for the fabrication of zirconia restorations for individual dental patients.
For staining, the zirconia materials must be immersed into the staining solution or brushed with the liquid before sintering at high temperature. The staining solution consists of two components: Type I - a color component (A、B、C、D、W、L、M、R、S、X), and Type II - an OP component, 1:1 collocation is recommended. These components are mixed together for use on the zirconia material to achieve the desired shade.

5.0 Indication for Use Statement

Biomic Color Opaque is liquid used for coloring pre-sintered zirconia restorations. It is used for the internal surface of dental zirconia material prosthesis.

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 appearance, uniformity, no foreign matter,flexural strength, chemical solubility and linear expansion coefficient and all tests were verified to meet acceptable criteria.

Biocompatibility Testing:
The nature of body contact of materials used in the design of the Biomic Color Opaque 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
- Subcutaneous Implant Test – ISO 10993-6
- Bacterial Reverse Mutation Test– ISO 10993-3
- TK Gene Mutation Test– ISO 10993-3
- Chemical Characterization Study-ISO 10993-18

Sterility and Shelf-Life Testing:
The device is provided non-sterile.
From the shelf life testing report, the Biomic Color Opaque has a shelf life of 18 months.

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 the subject and predicate devices.

Table 1- Comparison of Technology Characteristics

Item	Subject Device	Predicate Device	Remark
510(k) No.	K250534	K232676	--
Product Name	Biomic Color Opaque	Pre-Sintered Zirconia Coloring Liquid	--
Product Code	EIH	EIH	Same
Regulation No.	21 CFR 872.6660	21 CFR 872.6660	Same
Class	II	II	Same
Indications for Use	Biomic Color Opaque is liquid used for coloring pre-sintered zirconia restorations. It is used for the internal surface of dental zirconia material prosthesis.	It is only used for coloring Zirconia Denta Ceramics of our company to achieve clinical aesthetic restoration.	Same (Analysis 1)
Prescription Use	Yes	Yes	Same
Physical Form	Liquid	Liquid	Similar

Materials	Methylacryloyl propyl trimethoxy silane, deionized water, 1, 3-butanediol, ferric chloride, Citric acid, Cerium nitrate, Erbium nitrate, Cobaltous nitrate, Manganous acetate and Aluminum nitrate.	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%), Gluconi cacid (1%~2%), Citric acid (0%~1%) and Yttrium chloride (0~12%)	Different (Analysis 2)
Operation Principle	Mix Type I and Type II color (1:1 collocation)and brush or immerse zirconia dental ceramics in the mixed Biomic Color Opaque before sintering.	Brush or immerse zirconia dental ceramics with coloring liquid before sintering	Same
Physicochemical Properties	Complied with the standard ISO 6872 Dentistry – Dental Ceramics --Appearance, --Uniformity, --No Foreign Matter, --Flexural Strength, --Chemical Solubility --Linear Expansion Coefficient	Complied with the standard ISO 6872 Dentistry – Dental Ceramics	Same
Bottle Size	Various	Various	Same
Type of Packaging	Liquid container	Liquid container	Same
Color	A-OP,B-OP,C-OP,D-OP,W-OP,L-OP, M-OP,R-OP,S-OP,X-OP	O1, O2, O3, G1, G2, G3, P1, P2, P3, V1, V2, V3, TO1, TO2, TO3, TO4, BL1, BL2, BL3, BL4, 0M1, 0M2, 0M3.	Different (Analysis 3)
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
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, components and processing.
The subject device is different from the predicate device in the following:

1) While the wordings differ, the two descriptions essentially refer to the same intended use of the product, which is the application of liquid for coloring pre-sintered zirconia materials used in dental prostheses.
2) The minor difference between the materials of subject device and the predicate device will not cause any safety issues since the subject device has passed the biocompatibility test. Accordingly, it was concluded that the subject device is substantially equivalent in biocompatibility to the predicate device.
3) The color options refer to different shades or finishes, but do not change the device's function. Also, performance testing and biocompatibility test show the differences in color do not alter the fundamental safety, efficacy, or functional use of the 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.