October 29, 2026

Fanen New Materials Technology (Suzhou) Co., Ltd.
% Boyle Wang
General Manager
ABMED MEDICAL TECHNOLOGY PTY , Ltd.
48/6 Herbert St.
St Leonards, NSW 2065
AUSTRALIA

Re: K262756
Trade/Device Name: Zirconia Dental Ceramics and Staining Solution
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: August 3, 2026
Received: August 3, 2026

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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

Office of Industry and Consumer Education (OICE) to ask a question about a specific regulatory topic. See the OICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-office-industry-and-consumer-education-oice) for more information or contact OICE by email (AskOICE@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,
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Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K262756

Please provide the device trade name(s).

Zirconia Dental Ceramics and Staining Solution

Please provide your Indications for Use below.

Zirconia Dental Ceramics are used for dental restorations using different CAD/CAM or manual milling machines. All blanks are processed through dental laboratories or by dental professionals.
The staining solution is a liquid used for the complete or partial coloration of the Zirconia Dental Ceramics.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

K262756 -510(k) Summary

This summary is submitted in accordance with 21 CFR 807.92.

1.0 Submission Sponsor

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Date of Preparation: October 28,2026

2.0 Device Information

Trade name: Zirconia Dental Ceramics&Staining Solution
Common name: Dental Porcelain Powder
Staining Solution
Classification name: Porcelain Powder For Clinical Use
Production code: EIH
Regulation number: 21 CFR 872.6660
Classification: Class II
Panel: Dental

3.0 Identification of Predicate Device and Reference Device

Predicate Device #1:

510(k) Number: K222626
Trade/Product Name: Dental Zirconia Ceramic
Manufacturer: Aidite (Qinhuangdao) Technology Co., Ltd.

Predicate Device #2:

510(k) Number: K192723
Trade/Product Name: Coloring Liquid
Manufacturer: Aidite (Qinhuangdao) Technology Co., Ltd.

4.0 Device Description

The Subject Device contains Zirconia Dental Ceramics and Staining Solution.

Zirconia Dental Ceramics is a pre-colored zirconia composed of yttria-stabilized zirconia. It contains ZrO2+HfO2+Y2O3+Al2O3 and a very small amount of other inorganic pigments (Fe2O3+Er2O3+ Mn2O3). After sintering in the dental laboratory, these inorganic pigments make the restoration match the natural color of the patient's teeth.

Dental zirconia ceramics primarily come in 16 models, categorized mainly based on their flexural strength (i.e., ⩾500Mpa and ⩾800Mpa) and the overall color uniformity of the blank (i.e., single-layer and multi-layer). Each model also offers a variety of optional colors. Furthermore, this product provides a diverse range of shapes and sizes to accommodate different milling systems.

The proposed Zirconia Dental Ceramics is rendered based on the anatomical structure of the patient's teeth and is processed into dental restorations such as crowns, bridges, veneers, inlays, and onlays through CAD/CAM (Computer-Aided Design/Computer-Aided Manufacturing) methods or manual milling methods.

The staining solution is a liquid primarily composed of water and nitrates such as iron nitrate ($Fe(NO_3)_3$) and erbium nitrate ($Er(NO_3)_3$).

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 Dental Ceramics must be immersed into the staining solution or brushed with the liquid before sintering at high temperature.

The Staining Solution has 5 models: HT,ST,SHT,UT and 3D,and 16 shades:

A1,A2,A3,A3.5,A4,B1,B2,B3,B4,C1,C2,C3,C4,D2,D3,D4

The proposed equipment is intended for single use and is provided without sterilization. Its performance meets the standards of ISO 6872:2015/AMD 1:2018 "Dentistry: Ceramic Materials"

5.0 Indication for Use Statement

Zirconia Dental Ceramics are used for dental restorations using different CAD/CAM or manual milling machines. All blanks are processed through dental laboratories or by dental professionals.

The staining solution is a liquid used for the complete or partial coloration of the Dental Zirconia Ceramic.

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 uniformity, freedom from extraneous materials, Shrinkage factor, flexural solubility, chemical solubility, radioactivity, Linear expansion coefficient, and shade and all tests were verified to meet acceptable criteria.

Biocompatibility Testing:

The nature of body contact of materials used in the design of the Zirconia Dental Ceramics&Staining Solution 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
- Intracutaneous Reactivity Test – ISO 10993-23
- Acute Systemic Toxicity- ISO 10993-11
- Pyrogen Test- ISO 10993-11
- Subchronic Systemic Toxicity – ISO 10993-11
- Bacterial Reverse Mutation Test– ISO 10993-3
- Mouse Lymphoma Assay– ISO 10993-3
- Implantation– ISO 10993-6

Sterility and Shelf-Life Testing:

The device is provided non-sterile.

Accelerated aging studies were performed for both the Zirconia Dental Ceramics (claimed shelf life: 5 years) and the Staining Solution (claimed shelf life: 1 year)

The test results demonstrated that the aged Zirconia Dental Ceramics and Staining Solution continued to satisfy all applicable performance requirements, supporting the

claimed shelf life of 5 years and 1 year, respectively.

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 our device and the predicate devices.

Table 1- Comparison of Technology Characteristics for Zirconia Dental Ceramics

Item	Subject Device	Predicate Device 1	Substantive Equivalence Analysis
510(k) No.	K262756	K222626	/
Product Name	Zirconia Dental Ceramics	Dental Zirconia Ceramic	/
Product Code	EIH	EIH	Same
Regulation No.	21 CFR 872.6660	21 CFR 872.6660	Same
Class	II	II	Same
Intended Use/ Indication for Use	Zirconia Dental Ceramics are used for dental restorations using different CAD/CAM or manual milling machines. All blanks are processed through dental laboratories or by dental professionals.	Dental Zirconia Ceramic are used for dental restorations using different CAD/CAM or manual milling machines. All blanks are processed through dental laboratories or by dental professionals.	Same
Prescription Use	Yes	Yes	Same
Materials	Zirconia Dental Ceramics contains ZrO2+HfO2+Y2O3+ Al2O3 and a very small amount of other inorganic pigments (Fe2O3+Er2O3+Mn2O3); The staining solution is a liquid primarily composed of nitrates such as iron nitrate ($Fe(NO_3)_3$) and erbium nitrate ($Er(NO_3)_3$).	It contains ZrO2+HfO2+Y2O3+Al2O3 and very small amount of additional inorganic pigments (Fe2O3+Er2O3+Co3O4)	Similar (Analysis 1)
Conditions of use	This product is used by trained professional dentists.	This product is used by trained professional dentists.	Same
Physicochemical Properties	• Uniformity • Extraneous Materials	• Uniformity • Extraneous Materials	

Per ISO 6872 Dentistry – Dental Ceramics	• Shrinkage Factor, • Flexural Solubility, • Chemical Solubility, • Radioactivity, • Linear Expansion Coefficient, • Shade	• Shrinkage Factor, • Flexural Solubility, • Chemical Solubility, • Radioactivity, • Linear Expansion Coefficient, • Shade	Same
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
Applicable population	It is suitable for clinical patients with denture defect or absence.	It is suitable for clinical patients with denture defect or absence.	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 FDA guidance	Comply with ISO 10993-1:2018 and FDA guidance	Same

Analysis:

The subject device is highly similar to the predicate device in terms of indications for use, design, material and processing.
The subject device's components are slightly different from the predicate device in the following:

1) The main ingredients are similar, and the candidate product has passed the biocompatibility test, and there are no new risks. Accordingly, it was concluded that the subject device is substantially equivalent in biocompatibility to the predicate device.

Table 2- Comparison of Technology Characteristics for Staining Solution

Item	**Subject Device**	**Predicate Device 2**	**Substantive Equivalence Analysis**
510(k) No.	K262756	K192723	**/**
Product Name	Staining Solution	Coloring Liquid	/
Product Code	EIH	EIH	Same
Regulation No.	21 CFR 872.6660	21 CFR 872.6660	Same

Class	II	II	Same
Intended Use/ Indication for Use	The staining solution is a liquid used for the complete or partial coloration of the Dental Zirconia Ceramic.	Coloring Liquid is a liquid used for the complete or partial coloration of zirconia ceramic materials	Same
Prescription Use	Yes	Yes	Same
Ingredients	The staining solution is a liquid primarily composed of water and nitrates such as iron nitrate ($Fe(NO_3)_3$) and erbium nitrate ($Er(NO_3)_3$).	Coloring liquid are water-based coloring liquids, which consist of watery, acidic metal salt solutions.	Different (Analysis 2)
Operating Principle	Brush or immerse zirconia ceramic materials with coloring liquid before sintering	Brush or immerse zirconia ceramic materials with coloring liquid before sintering	Same
Conditions of use	This product is used by trained professional dentists.	This product is used by trained professional dentists.	Same
Bottle size	Various	Various	Same
Shade	Various	Various	Same
Sterile	Non-sterile	Non-sterile	Same
Biocompatibility	Comply with ISO 10993-1:2018 and FDA guidance	Comply with ISO 10993-1:2018 and FDA guidance	Same

Analysis:

2) Although the Subject Device uses ferric nitrate ($Fe(NO_3)_3$) and erbium nitrate ($Er(NO_3)_3$) as the primary coloring components, while the predicate device uses acidic metal salt solutions, both devices employ the same water-based staining principle and are intended for coloring zirconia restorations prior to sintering. During the high-temperature sintering process, the coloring components diffuse into and become incorporated within the zirconia matrix. Therefore, the final patient-contacting component is the sintered zirconia restoration rather than the staining solution itself. Biocompatibility testing was performed using representative stained and sintered zirconia specimens prepared according to the intended manufacturing process, representing the final finished device in clinical use. The biological evaluation demonstrated that the final patient-contacting material is biocompatible and does not raise different questions of safety or effectiveness.

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.