April 11, 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: K250811
Trade/Device Name: Dental Zirconia Ceramic
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: March 17, 2025
Received: March 17, 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,

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

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.	K250811

Please provide the device trade name(s).

Dental Zirconia Ceramic

Please provide your Indications for Use below.

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.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

K250811

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: Feb.28,2025

2.0 Device Information

Trade name: Dental Zirconia Ceramic
Common name: Dental Zirconia Ceramics
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:

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

4.0 Device Description

Dental Zirconia Ceramic is pre-shaded zirconia, and it's composed of yttria-stabilized zirconia. It contains ZrO_2+HfO_2+Y_2O_3+Al_2O_3 and very small amount of additional inorganic pigments (Fe_2O_3+Er_2O_3+Co_3O_4). The inorganic pigments generate the color on the restorations, after sintering at dental labs, that matches natural color of patient's teeth.

Dental Zirconia Ceramic has 19 models mainly according to the flexural strength (i.e. ≥600Mpa and ≥800Mpa) and the shade uniformity in the whole blank (i.e. monolayer and multilayer). Each model also has several available shade variations. And it also offers various shapes and dimensions suitable for different milling systems.

The proposed device is processed into the dental restorations such as crowns, bridges, veneers, inlays and onlays based on the anatomical rendering of the patient's teeth using CAD/CAM (computer aided design / computer aided manufacturing) method or manual milling method.

The proposed device is a single-use device, provided non-sterile, and its performance conforms to ISO 6872:2015/AMD 1:2018 Dentistry: Ceramic Materials.

5.0 Indication for Use Statement

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.

6.0 Non-clinical Test Conclusion

Physical and mechanical properties of the subject device were evaluated according to ISO 6872:2015/AMD 1:2018 and ISO 13356:2015.

According to ISO 6872, the subject device is classified into the following:
Type II: All other forms of ceramic products.
Class 4: Monolithic ceramic for prostheses involving partially or fully covered substructure
Class 5: Monolithic ceramic for prostheses involving partially or fully covered substructure for four or more units.

Biocompatibility testing was performed to verify the equivalent safety of the materials that are used.

7.0 Technological Characteristics

Principle of Operation

There is no change in the principle of operation as part of this submission from the previous clearance under K222626. The module still utilizes the same principles of operation for Dental Zirconia Ceramic governed by the following principles:

The proposed device is composed of yttria-stabilized zirconia, it has good physical properties, stable chemical properties and good biocompatibilities, and it's suitable to prepare the dental restorations. When preparing the restoration, the patient's dental model is obtained by the doctor. Based on the desired shape of the restoration, the zirconia block is processed using a proper milling machine.

8.0 Summary of Technological Characteristics of the Subject Device Compared to the Predicate Device

The subject device, Dental Zirconia Ceramic (Model: Muitilayer-3D, UTC, UTM, Multilayer3D pro, SHTPC, SHTPM, SHT-Plus, HT, ST, SHT, AT, COLOR, ST-COLOR, Multilayer,Multilayer-3T, MC, FC, GC, EC) and the predicate device -Dental Zirconia Ceramic (Model: Muitilayer-3D, UTC, UTM, Multilayer3D pro,SHTPC, SHTPM), have the following key similarities:

- Both devices have the same intended use
- Both devices are indicated for the same patient population
- Both devices have the same principle of operation and mechanism of action

The modifications outlined in this subject device do not raise different questions of safety or effectiveness as demonstrated by performance testing using the same methods based on the FDA-recognized standard ISO 6872 that were utilized for the predicate device. Furthermore, these changes (1) do not affect the intended use or (2) alter the fundamental scientific technology of the device. The modified devices retain the same core technological characteristics as the predicate device.

9.0 Summary of Clinical Test

Clinical testing was not required for this submission.

10.0 Technological Characteristics and Substantial Equivalence

The following table shows similarities and differences of use, design, and material between our device and the predicate devices.

Table1 General Device Characteristics Comparison Table

Item	Subject Device	Predicate device	Remark
510(k) No.	K250811	K222626	
Product Name	Dental Zirconia Ceramic	Dental Zirconia Ceramic	--
Product Code	EIH	EIH	Same
Regulation No.	872.6660	872.6660	Same
Class	II	II	Same
Intended Use/Indication for Use	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.	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
Class (per ISO 6872:2015)	Class 4: Multilayer-3D, UTC, UTM, AT, Multilayer. Class 5: Multilayer-3D pro, SHTPC, SHTPM, SHT-Plus, HT, ST, SHT, COLOR, ST-COLOR, Multilayer-3T, MC, FC, GC, EC.	Class 4: Multilayer-3D, UTC, UTM, Class 5: Multilayer-3D pro, SHTPC, SHTPM	Different*
Composition	Based on yttria-stabilized zirconia	Based on yttria-stabilized zirconia	Same
Color	Various Color	Various Color	Same
Intended User	Professional dental technicians	Professional dental technicians	Same
Dimension	Various	Various	Same
Single Use	Yes	Yes	Same
Sterile	Non-sterile	Non-sterile	Same
Physical Properties	Conform to ISO 6872	Conform to ISO 6872	Same
Biocompatibility	Comply with ISO 7405:2018 ,ISO 10993-1:2018, FDA Guidance	Comply with ISO 7405:2018 ,ISO 10993-1:2018, FDA Guidance	Same

Analysis*:

The subject device is same to the predicate device in terms of indications for use, design, material and processing.

The subject device is different from the predicate device in the following:

1) Add a new model " SHT-Plus, HT, ST, SHT, COLOR, ST-COLOR, Multilayer-3T, MC, FC, GC, EC, AT and Multilayer " to the predicate device.

   The components of each model and each registered color number are basically the same, only the content of each component is slightly different.

   Physical and mechanical property of the new model is performed per ISO 6872. Both the subject device and the predicate device have same physical/mechanical properties that met the requirements of ISO 6872.

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.