July 12, 2024

Aidite (Qinhuangdao) Technology Co., Ltd.
% Boyle Wang
General Manager
Shanghai Truthful Information Technology Co., Ltd.
Room 1801, No. 161 East Lu Jiazui Rd.,
Pudong, 200120
China

Re: K241715
Trade/Device Name: Dental Glass Ceramics Blocks (HT,LT,ST)
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: June 14, 2024
Received: June 14, 2024

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.

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,

FDA

Bobak Shirmohammadi -S

For 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241715

Device Name

Dental Glass Ceramics Blocks (HT,LT,ST)

Indications for Use *(Describe)*

Dental Glass Ceramics Blocks 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

K241715

This summary is submitted in accordance with 21 CFR 807.92.

1.0 Submission Sponsor

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Date of Preparation: Jul.11,2024

2.0 Device Information

Trade name: Dental Glass Ceramics Blocks
Common name: Dental Glass 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: K192231
Trade/Product Name: Dental Glass Ceramics Blocks
Manufacturer: Aidite (Qinhuangdao) Technology Co., Ltd.

4.0 Device Description

Dental Glass Ceramics Blocks are derived from dental porcelain powder that has been processed into their final net shapes. These blanks are then being further fabricated (using hot press or CAD/CAM technologies) into all-ceramic restorations such as veneers, inlay/ onlay, partial crowns, anterior crowns, posterior crowns. The ceramics material is composed of SiO_2, Li_2O, K_2O, Al_2O_3 and other oxides. It also contains inorganic pigments to provide different shades on the product surface. It has three model: HT,LT,ST, and totally 23 colors(A1,A2,A3,A3.5,A4,B1,B2,B3,B4,C1,C2, C3,C4,D2,D3,D4,BL1,BL2,BL3,BL4, OM1, OM2 and OM3).
The performance of Dental Glass Ceramics Blocks conforms to ISO 6872:2015/AMD 1:2018 Dentistry: Ceramic Materials.

5.0 Indication for Use Statement

Dental Glass Ceramics Blocks 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.

6.0 Non-clinical Test Conclusion

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

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

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 K192231. The module still utilizes the same principles of operation for Dental Glass Ceramics Blocks governed by the following principles:

This product is made of silicon dioxide powder. It is made by high temperature melting, casting molding and high temperature nucleation. Professional dental restoration agencies make the forms fitting for patients by hot press moulding or CAD/CAM and

install it into the place to be repaired after sintering. It gets excellent biocompatibility, aesthetic appearance after sintering.

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

The subject device, Dental Glass Ceramics Blocks (Model: HT, LT, ST) and the predicate device Dental Glass Ceramics Blocks (Model: Hot press model and CAD/CAM model), have the following key similarities:

- Both devices have the same intended use
- Both devices have the same components and shades.
- 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.	K241715	K192231	
Product Name	Dental Glass Ceramics Blocks	Dental Glass Ceramics Blocks	--
Product Code	EIH	EIH	Same
Regulation No.	872.6660	872.6660	Same
Class	II	II	Same
Intended Use/Indication for Use	Dental Glass Ceramics Blocks 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 Glass Ceramics Blocks 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.	Same
Prescription Use	Yes	Yes	Same
Shapes	Blocks	Blocks	Same
Color	Various Color	Various Color	Same
Materials	SiO2, Li2O, K2O, Al2O3 and other oxides	SiO2, Li2O, K2O, Al2O3 and other oxides	
Dimension	Various	Various	Same
Processing at Dental lab	Hot Press (Up. Press Series) CAD/CAM (Up.CAD Series)	Hot Press (Up. Press Series) CAD/CAM (Up.CAD Series)	Same
Model	HT, LT, ST	Hot press model, CAD/CAM model	Different*
Density(g/cm^3)	Meet the requirements of ISO 6872:2018	Meet the requirements of ISO 6872:2018	Same
Flexural Strength(MPa)			
Radioactive ($Bq \cdot g^{-1}$)			
Coefficient of Thermal Expansion (K-1)			
Glass Transition Temperature(°C)			
Single Use	Yes	Yes	Same
Sterile	Non-sterile	Non-sterile	Same
Biocompatibility	Comply with ISO 10993-1:2018, FDA Guidance	Comply with ISO 10993-1, 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) The model name has been changed for the subject device from the predicate device. Specifically, the predicate device's model name "Hot press model" has been changed to "HT model," and the model name "CAD/CAM model" has been changed to "LT model." It's just model name change, it has no effect on the substantial equivalence.
2) Add a new model "ST" to the predicate device's "CAD/CAM model."

   HT model is high translucency ceramic block. LT model is low translucency ceramic block. And the new model ST model is super translucency ceramic block.

   The only difference between ST and LT and HT is their aesthetic effect, while the rest of their performance remains unchanged.

   Physical and mechanical property of the new model ST 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.