



December 1, 2023

Aibodent Biotechnology Co., Ltd
% Shanfeng Jiang
Regulation Control Manager
Guangzhou Junyi Information Technology Co., Ltd.
Room 304, Building A, No. 62 Nanyun 2nd Road, Science Town
Huangpu District, Guangzhou City, Guangdong 510663
CHINA

Re: K232438
Trade/Device Name: Dental Glass Ceramics Blocks
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: November 3, 2023
Received: November 3, 2023

Dear Shanfeng Jiang:

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

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

510(k) Number (if known)
K232438

Device Name
Dental Glass Ceramics Blocks

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.

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Section 5 - 510(k) Summary

K232438

Date of Summary Preparation: August 14, 2023

Date of Modification: November 29, 2023

1. Submitter's Identifications

1. Submitter's Name: Aibodent Biotechnology Co., Ltd
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2. Correspondent's Identifications

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3. Name of the Device

Device Classification Name: Powder, Porcelain
Regulation Description: Porcelain powder for clinical use
Trade Name: Dental Glass Ceramics Blocks
Model: HT, LT
Regulation Medical Specialty: Dental
Review Panel: Dental
Product Code: EIH
Regulation Number: 21 CFR 872.6660
Device Classification: Class II

4. The Predicate Devices

Predicate device: K192231 Dental Glass Ceramics Blocks Aidite (Qinhuangdao)
Technology Co., Ltd.

5. 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 SiO₂, Li₂O, K₂O, Al₂O₃ and other oxides. It also contains inorganic pigments to provide different shades on the product surface.

The performance of the dental blanks conforms to ISO 6872, *Dentistry — Ceramic materials*.

6. Indications 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.

7. Summary of Substantial Equivalence

Table 1 Comparison to Predicate Device

	Proposed Device	Predicate device	Comparison
510k Number		K192231	-----
Product Code	EIH	EIH	Same
Proprietary Name	Dental Glass Ceramics Blocks	Dental Glass Ceramics Blocks	-----
Model:	HT, LT	-----	-----
Manufacturer	Aibodent Biotechnology Co., Ltd	Aidite (Qinhuangdao) Technology Co., Ltd.	-----
Indications 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	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	Same

	or CAD/CAM system.	or CAD/CAM system.	
Materials	SiO ₂ , Li ₂ O, K ₂ O, Al ₂ O ₃ and other oxides.	SiO ₂ , Li ₂ O, K ₂ O, Al ₂ O ₃ and other oxides.	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
Geometry	Blocks	Blocks	Same
Dimension	Various	Various	Same
Single Use	Yes	Yes	Same
Available color	Various	Various	Same
Sterile	Non-sterile	Non-sterile	Same
Radioactivity (Bq·g-1)	Meet the requirements of ISO6872:2015	Meet the requirements of ISO6872:2015	Same
Density(g/cm3)	Meet the requirements of ISO6872:2015	Meet the requirements of ISO6872:2015	Same
Flexural Strength(MPa)	Meet the requirements of ISO6872:2015	Meet the requirements of ISO6872:2015	Same
Coefficient of Thermal Expansion (K-1)	Meet the requirements of ISO6872:2015	Meet the requirements of ISO6872:2015	Same
Glass Transition Temperature(°C)	Meet the requirements of ISO6872:2015	Meet the requirements of ISO6872:2015	Same
Cytotoxicity (ISO10993-5:2009)	No cytotoxicity effect	No cytotoxicity effect	Same
Irritation Oral Mucosa Irritation(ISO10993-10:2010)	Not a primary oral mucosa irritant under the conditions of the study	Not a primary oral mucosa irritant under the conditions of the study	Same
Sensitization(ISO 10993-10:2021)	Not a sensitizer under the conditions of the study	Not a sensitizer under the conditions of the study	Same

Subacute and Subchronic Toxicity(ISO10993-11:2006)	No subacute and subchronic toxic effects observed	No subacute and subchronic toxic effects observed	Same
Genotoxicity (ISO10993-3:2003)	No genotoxic effects observed	No genotoxic effects observed	Same
Discussion for Substantially Equivalent (SE)	The proposed device is essentially identical to the predicate devices in terms of indication for use, design between our device and the predicate devices.		

The proposed device is essentially identical to the predicate devices in terms of indication for use, design between our device and the predicate devices.

8. Summary of Non-Clinical Testing

Bench testing was performed per ISO 6872:2015 and internal procedures to ensure that the Dental Glass Ceramics Blocks met its specifications. All tests were verified to meet acceptance criteria. Test results on radioactivity, dimension, flexural strength, chemical solubility, linear thermal expansion coefficient, freedom from extraneous materials, uniformity, glass transition temperature, sintering density and fracture toughness of the subject device are very similar to predicate device. Biocompatibility testing was performed to verify the equivalent safety of the materials that are used.

According to ISO 10993-1:2018, we evaluated and conducted the compatibility test for the proposed device.

9. Clinical Test Conclusion

No clinical study is included in this submission.

10. Conclusion:

The conclusions drawn from the nonclinical tests demonstrate that subject device Dental Glass Ceramics Blocks performs as well as or better than the legally marketed predicate device K192231 Dental Glass Ceramics Blocks. Dental Glass Ceramics Blocks is substantial equivalent to the legally marketed predicate device K192231 Dental Glass Ceramics Blocks.