November 13, 2024

Hunan Vsmile Biotechnology Co., Ltd.
Xiaomi Tang
General Manager
Room.1202-1203, Huanchuang Enterprise Square
Building A4 No.2450 Yuelu West Avenue
Hi-tech Development District Changsha, Hunan 410000
CHINA

Re: K242407
Trade/Device Name: Dental Glass Ceramics Blocks (HT, LT, MT)
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: August 14, 2024
Received: August 14, 2024

Dear Xiaomi Tang:

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

Michael E. Adjodha, MChE, RAC, CQIA
Assistant Director
DHT1B: Division of Dental and
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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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K242407

Device Name

Dental Glass Ceramics Blocks (HT、LT、MT)

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

510(k) Number : K242407
Date of Summary Preparation: November 12, 2024

1. Submitter's Identifications

Submitter's Name: Hunan Vsmile Biotechnology Co., Ltd.
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2. Correspondent's Identifications

Correspondent's Name: Guangzhou Junyi Information Technology Co., Ltd.
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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, MT
Regulation Medical Specialty: Dental
Review Panel: Dental
Product Code: EIH
Regulation Number: 21 CFR 872.6660
Device Classification: Class II

4. The Predicate Devices

Primary 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 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.

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

Notes: Dental Glass Ceramic Blocks are not suitable for three-unit restorations for molars and restorations with four or more units

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, MT	------	------
Manufacturer	Hunan Vsmile 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	Dental Glass Ceramics Blocks are indicated for fabricating all-ceramic restorations such as veneers, inlay/ onlay, partial crowns, anterior crowns, posterior	Same

	crowns, using the hot press technique or CAD/CAM system.	crowns, using the hot press technique or CAD/CAM system.	
Materials	SiO_2, Li_2O, K_2O, Al_2O_3 and other oxides.(Refer to the device description)	SiO_2, Li_2O, K_2O, Al_2O_3 and other oxides.（unknown）	Different
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	Not a sensitizer	Not a sensitizer	Same

10993-10:2021)	under the conditions of the study	under the conditions of the study	
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 subject device and predicate device may have slight differences in other components, but the main components are SiO_2, Li_2O, K_2O, and Al_2O_3, which are the same. Despite these differences, the test results according to ISO 6872 show that the test device is essentially equivalent to the equivalent device and meets the necessary requirements in terms of physical and chemical properties.		

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 is as safe and effective as the predicate device. Dental Glass Ceramics Blocks is substantial equivalent to the legally marketed predicate device K192231 Dental Glass Ceramics Blocks.