July 8, 2020

Aidite (Qinhuangdao) Technology Co., Ltd.
% Christy Young
Consultant
Shenzhen Joyantech Consulting Co., Ltd
NO. 55 Shizhou middle road , Nanshan District
Shenzhen, Guangdong
GD755, China

Re: K192231
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: May 22, 2020
Received: June 8, 2020

Dear Christy Young:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

For Srinivas “Nandu” Nandkumar, Ph.D.
Director
DHT1B: Division of Dental 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192231

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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510(k) Summary K192231

1. Contact Details

1.1 Applicant information

Applicant Name	Aidite (Qinhuangdao) Technology Co., Ltd.
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Date Prepared	May 28, 2019
Website	www.zro2blocks.com

1.2 Submission Correspondent

卓远天成	Shenzhen Joyantech Consulting Co., Ltd Room 1122, International Mayors Communication Centre, No. 55 Shizhou middle road , Nanshan District, Shenzhen
Phone No.	+86-755-86069197
Contact person	Christy Young; Field Fu;
Contact person's e-mail	christy@cefda.com; cefda@foxmail.com
Website	http://www.cefda.com

2. Device information

Trade name	Dental Glass Ceramics Blocks
Common name	Dental Glass Ceramics
Model	/
Classification	Ⅱ
Classification name	Porcelain Powder for Clinical Use
Product code	EIH
Regulation No.	872.6660

3. Legally Marketed Predicate Device

Trade Name	Dental Lithium Disilicate Glass Ceramic Block(Up.Press Series and Up. CAD Series)
510(k) Number	K141727
Product Code	EIH
Manufacturer	Liaoning Upcera Co., Ltd

4. 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.

5. 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.

6. Substantial Equivalence Comparison

Item	**Proposed Device: Dental Glass Ceramics Blocks**	**Predicate Device: Dental Lithium Disilicate Glass Ceramic Block(Up.Press Series and Up. CAD Series) (K141727)**	**Comments**
Product Code	EIH	EIH	Same
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.	Dental Lithium Disilicate Glass Ceramic Blocks (Up. Press Series and Up. CAD Series) are indicated for fabricating allceramic restorations such as veneers, inlay/onlay, partial crowns, anterior crowns, posterior crowns, using the hot press technique or CAD/CAM system.	Same
Materials	SiO_2, Li_2O, K_2O, Al_2O_3 and other oxides	SiO_2, Li_2O, K_2O, P_2O_5, Al_2O_3, B_2O_3, and other oxides	Comparable(Issue 1)
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, disc and rod	Similar
Dimension	Various	Various	Same
Single use	Yes	Yes	Same
Available color	Various	Various	Same
Sterile	Non-sterile	Non-sterile	Same
Radioactivity ($Bq \cdot g^{-1}$)	Meet the requirements of ISO 6872:2015	Meet the requirements of ISO 6872:2008	Same
Density(g/cm^3)			
Flexural Strength(MPa)			

Coefficient of Thermal Expansion (K^{-1}) Glass Transition Temperature(° C)			
Cytotoxicity (ISO 10993-5:2009)	No cytotoxicity effect	No cytotoxicity effect	Same
Irritation Oral Mucosa Irritation (ISO 10993-10:2010)	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 10993-10:2010)	Not a sensitizer under the conditions of the study	Not a sensitizer under the conditions of the study	Same
Subacute and Subchronic Toxicity(ISO 10993-11:2006)	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

Issue 1:

The subject device and the predicate devices might have a slight difference in compositions but all the devices have SiO_2, Li_2O, K_2O and Al_2O_3 as major components. Despite this difference, the test results per ISO 6872 shows that the subject device is substantially equivalent to the predicate device in physical and chemical properties and meets the necessary requirements.

7. 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.

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

8. Clinical testing

Clinical testing was not performed for the proposed device.

9. Conclusion

It has been shown in this 510(k) submission that Dental Glass Ceramics Blocks and its predicate devices have the similar indications for use, similar composition, similar biocompatibility, and similar performance.

The difference between Dental Glass Ceramics Blocks and its predicate device do not raise any

question regarding its safety and effectiveness.

Dental Glass Ceramics Blocks, as designed and manufactured, is as safe and effective as its predicated device, and therefore is substantially equivalent as its predicate device.