March 8, 2023

Aidite (Qinhuangdao) Technology Co., Ltd
℅ Julie Chen
Consultant
ICAS Group
155 Pingbei Rd,Minghang
Shanghai, Shanghai 201100
CHINA

Re: K223742
Trade/Device Name: Dental Ceramic Blocks
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: Class II
Product Code: EBF
Dated: December 7, 2022
Received: December 29, 2022

Dear Julie Chen:

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,

Michael E. Adjodha -S

Michael E. Adjodha, M.ChE.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K223742

Device Name

Dental Ceramic Blocks

Indications for Use *(Describe)*

Dental Ceramic Blocks are indicated for fabrication of inlays/onlays,laminate veneers,anterior and posterior full crown restorations, and implant crowns and bridges by dental professionals and manufacturers using a dental 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K223742
510(K) Summary

I. SUBMITTER:

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Summary prepared：02/27/2023

II. DEVICE

Name of Device: Dental Ceramic Blocks
Regulation Number: 21 CFR PART 872.3690
Classification Name: Material, tooth shade, resin
Regulatory Class: II
Product Code: EBF

III. PREDICATE DEVICE

Primary predicate device: K222723(AMBARINO High-Class)

IV. DEVICE DESCRIPTION

Dental Ceramic Blocks consist of methacrylate, benzoyl peroxide, barium glass powder and pigmen to form a solid block of material. The unique marriage of the materials creates a dual-network hybrid, which lends the positive physical properties of each individual material to the other. This non-sterile material is milled in a dental CAD/CAM machine into restorative form for single patient use. Dental Ceramic Blocks is provided as non-sterile.

V. AVAILABLE MODEL

Model	Shade	Specification
Monochromatic	A1-HT, A2-HT, A3-HT, A3.5-HT, A4-HT, B1-HT, B2-HT, B3-HT, B4-HT, C1-HT, C2-HT, C3-HT, C4-HT, D2-HT, D3-HT, D4-HT, BL1-HT, BL2-HT, BL3-HT, BL4-HT；A1-LT, A2-LT, A3-LT, A3.5-LT, A4-LT, B1-LT, B2-LT, B3-LT, B4-LT, C1-LT, C2-LT, C3-LT, C4-LT,D2-LT, D3-LT, D4-LT, BL1-LT, BL2-LT, BL3-LT, BL4-LT	Disc shape：16×16, 20×20, 98×10, 98×12, 98×14, 98×16, 98×18, 98×20, 98×22, 98×25, 98×28, 98×30,95×10, 95×12, 95×14, 95×16, 95×18, 95×20, 95×22, 95×25, 95×28, 95×30（Unit: mm） Horseshoe：92×75×12、92×75×14、92×75×15、92×75×16、92×75×18、92×75×20（Unit: mm） Rectangle：55×15.5×19、55×15.5×14、40×15×14、40×15×15、40×15×19、32×15×15、29×15×14、20×12×12、20×15×14、20×15×19、18×16×18、18×14.5×14.5、18×13×15、18×14×12、15.5×11×13、15×8×8、15×10×8、15×12×10、14×12×10（Unit: mm）
Multi-Layered		

VI. INTENED USE per 21CFR 807.92(A)(5)

Dental Ceramic Blocks are indicated for fabrication of inlays/onlays, laminate veneers, anterior and posterior full crown restorations, and implant crowns and bridges by dental professionals and manufacturers using a dental CAD/CAM system.

VII. INDICATIONS for USE

Dental Ceramic Blocks are indicated for fabrication of inlays/onlays, laminate veneers, anterior and posterior full crown restorations, and implant crowns and bridges by dental professionals and manufacturers using a dental CAD/CAM system.

VIII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Dental Ceramic Blocks are compared with the predicate device, AMBARINO High-Class (K222723). The results are shown below in the Technological Characteristics Comparison Table:

Item	**Proposed Device** Dental Ceramic Blocks	**Predicate Device** AMBARINO® High-Class	**Remark**
K number	TBD	K222723	--
Regulation Number	21 CFR PART 872.3690	21 CFR PART 872.3690	SE
Product Code	EBF	EBF	SE
Common name	Material, tooth shade, resin	Material, tooth shade, resin	SE
Classification	II	II	SE
Manufacturer	Aidite (Qinhuangdao) Technology Co., Ltd	Creamed GmbH & Co. Produktions- und Handels KG	--
Intended Use	Dental Ceramic Blocks are indicated for fabrication of inlays/onlays, laminate veneers, anterior and posterior full crown restorations, and implant crowns and bridges by dental professionals and manufacturers using a dental CAD/CAM system.	AMBARINO® High-Class is indicated for fabrication of inlays / onlays, laminate veneers, anterior and posterior full crown restorations, and implant crowns and bridges by dental professionals and manufacturers using a dental CAD/CAM system.	SE
Type Use	Prescription (Rx Only)	Prescription (Rx Only)	SE
Physical State	Cured blocks and discs in a variety of shapes and shades	Cured blocks and discs in a variety of shapes and shades	SE
Shapes	Disc Shape and Retangle	Disc Shape and Retangle	SE
Structure	Polymer resin /ceramic hybrid composite	Polymer resin /ceramic hybrid composite	SE
Color	Color	Color	SE

Materials	UDMA, TEGDMA , EGDMA BPO, 72% Barium glass powder, Gaseous silica, TiO_2, Fe_2O_3, $Fe_2O_3 \cdot H_2O$, Fe_3O_4	39% UDMA, TEGDMA 61% inorganic silica-based glass and silica	Note 1
Dimension	Various	14, 98	Note 2
Flexural Strength	207 MPa	191 MPa	Note 3
Radioactive	2.3mm AI	1.8mm AI	Note 3
Biocompatibility	Conforms with ISO 10993-1, FDA Guidance	Conforms with ISO 10993-1, FDA Guidance	SE
Performance	Conforms with ISO 4049	Conforms with ISO 4049	SE
Sterility	Non-Sterile	Non-sterile	SE
Single Use	Single Use	Single Use	SE

Discussion

Note 1 Material

Although the material of the proposed device and the predicate device is different, they meet the requirement of ISO 10993-1 and FDA guidance.

Note 2 Dimension & Note 3 Flexural Strength and Radioactive

The performance testing of the proposed device and the predicate device is complied with ISO 4049 and ISO 7491. Although the results have slightly difference, they meet the acceptance criteria. Therefore, this difference is considered not to affect the Substantially Equivalency (SE) between the proposed and predicate devices.

IX. PERFORMANCE DATA

Non-Clinical Performance Test Conclusion

Biocompatibility

Biocompatibility testing was performed on the proposed device in accordance with the following standards:

- ISO 10993-5:2009 Biological evaluation of medical devices- Part 5: Test for in vitro cytotoxicity
- ISO 10993-10:20101Biological evaluation of medical devices- Part 10: Test for irritation and delayed-type hypersensitivity

- ISO 10993-11:2017 Biological evaluation of medical devices Part 11: Tests for systemic toxicity
- ISO 10993-6 ：2016 Biological evaluation of medical devices -- Part 6: Tests for local effects after implantation
- ISO 10993-3：2014 Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity, and reproductive toxicity

Performance Bench Testing

The basic safety and essential performance comparison test were evaluated based on as following standards:

- ISO 4049, Dentistry – Polymer-based Restorative Materials
- ISO 7405, Dentistry – Evaluation of biocompatibility of medical device used in dentistry

Animal Study

Animal testing was not required for this submission.

Clinical Studies

No clinical study is included in this submission.

X. CONCLUSIONS

The conclusions drawn from the nonclinical tests demonstrate that the proposed device is as safe, as effective, and performs as well as or better than the legally marketed predicate device AMBARINO High-Class (K222723).