



July 9, 2024

Hunan Hualian Special Ceramics Co., Ltd.
% Jennifer Liu
Regulatory Affairs Manager
Chenhe Medical Consulting Co., Ltd
Room 113, 7th Floor, Block B, Building 1
No. A 38, Zhongguancun Street, Haidian District
Beijing,
China

Re: K241316
Trade/Device Name: Zirconia Block
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain powder for clinical use
Regulatory Class: Class II
Product Code: EIH
Dated: May 10, 2024
Received: May 10, 2024

Dear Jennifer Liu:

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,

The logo of the U.S. Food and Drug Administration (FDA) is displayed in a light blue color. It consists of the letters "FDA" in a bold, sans-serif font, with the "F" and "D" being larger and more prominent than the "A".

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

Indications for Use

510(k) Number (if known)

K241316

Device Name

Zirconia Block

Indications for Use (Describe)

HT, HT-C, ST, ST-C, ST-ML, SHT, SHT-C, SHT-ML: used to make the crown, bridge, inlay, veneer of the all-porcelain restoration.

UT, UT-C, UT-ML and 3D-PRO: used to make the crown, maximum 3-unit bridge, inlay, veneer of the all-porcelain restoration.

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**510(k) Summary - K241316**

This summary of 510(k) for the subjective device equivalence information is being submitted in accordance with the requirements of 21 C.F.R. 807.92.

1. **Date Summary Prepared:** May 6, 2024

2. **Contact details**

2.1 Applicant information:

Name	Hunan Hualian Special Ceramics Co.,ltd
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2.2 Submission Correspondent

Name	Chenhe Medical Consulting Co., Ltd
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Tel:	086 633 13774915658
Contact person and title:	Jennifer Liu/Regulatory Affairs Manager
E-mail	Jennifer19862022@163.com

3. **Device Name**

Trade name: Zirconia Block

Classification name: Powder, Porcelain

Regulatory Class: II

Product Code: EIH

4. **Predicate Device Information**

Table 1: Predicate Device Information				
Owner/Operator	Device Trade Name	510 (k) No.	Product Code	Predicate
Aidite (Qinhuangdao) Technology Co., Ltd.	Dental Zirconia Ceramic	K222626	EIH	Primary

This predicate device has not been subject to a design-related recall.

No reference devices were used in this submission.

5. Description of Device

Zirconia Block is used for dental restorations, such as crown, bridge, inlay, veneer, using CAD/CAM or manual milling machines. The main ingredients of the product include zirconia, yttrium oxide, hafnium oxide, alumina and other oxides. Through the digital scanning of the tooth or tooth mold, the three-dimensional data of the tooth mold is obtained. According to the data, the CAD design is carried out to design the porcelain block processing model. Then CNC machine tool was used to make CAM according to the porcelain block processing model, and the inner crown of all-porcelain denture was made by air sintering or vacuum sintering, so as to achieve the strength and aesthetic effect required by clinical use. Finally, the inner crown of the all-porcelain denture was glazed with porcelain powder to form the combination of porcelain, and the all-porcelain denture was made.

6. Indications for Use

HT, HT-C, ST, ST-C, ST-ML, SHT, SHT-C, SHT-ML: used to make the crown, bridge, inlay, veneer of the all-porcelain restoration.

UT, UT-C, UT-ML and 3D-PRO: used to make the crown, maximum 3-unit bridge, inlay, veneer of the all-porcelain restoration.

7. Summary of Physical and Chemical Properties Tests

Test standards and methods based on ISO 6872:2015 (Dentistry - Ceramic materials). And the results from testing demonstrate that Zirconia Block is substantially equivalent to the predicate device.

8. Technological Characteristics

All components of the subject device are based upon industry well-known chemistry. The following table shows the significant technological characteristics for the subject device and indicates the following similarities and differences with the predicate device:

Table 4: Technological Characteristics Comparison Table

Technological Characteristics	Subject device Zirconia Block	Primary predicate Aidite (Qinhuangdao) Technology Co., Ltd. Dental Zirconia Ceramic K222626
Product code	EIH	EIH
Indications for Use	HT, HT-C, ST, ST-C, ST-ML, SHT, SHT-C, SHT-ML: used to make the crown, bridge, inlay, veneer of the all-porcelain restoration. UT, UT-C, UT-ML and 3D-PRO: used to make the crown, maximum 3-unit bridge, inlay, veneer of the all-porcelain restoration.	Dental Zirconia Ceramic are used for dental restorations using different CAD/CAM or manual milling machines. All blanks are processed through dental laboratories or by dental professionals.
Composition	ZrO ₂ , Y ₂ O ₃ , Al ₂ O ₃ and other oxides	ZrO ₂ , Y ₂ O ₃ , Al ₂ O ₃ and other oxides
Pressing at Dental lab	Sintering Press CAD/CAM	Sintering Press CAD/CAM
Dimension	Various	Various
Single use	Yes	Yes
Available Color	Various	Various
Sterile	Non-sterile	Non-sterile
Physical Properties	The subject device and the predicate device have substantially equivalent physical property as they all conform to the specifications set by internal final inspection and the test method equal to ISO 6872:2015.	

9. Summary of Biocompatibility

The new device, Zirconia Blocks, is substantially equivalent to the predicate devices that have been legally marketed for decades and with no clinical adverse events. The formulation of new device does not contain any non-conventional chemicals compared to the legally marketed predicate device.

Biocompatibility tests were performed fully following the ISO 10993 standards. The test items include Cytotoxicity, Sensitization, Irritation, Systemic Toxicity, Subchronic Toxicity and Genotoxicity.

10. Clinical Performance Data

Not applicable. Clinical performance testing has not been performed for the subject device.

11. Conclusions

Based on the indications for use, technological characteristics, performance testing and comparison to predicate devices, the subject device has been shown to be safe and effective for its intended use and the minor differences in indications for use fall within the intended use of the predicate devices affecting neither the general intended use nor substantial equivalence. Hunan Hualian Special Ceramics Co.,Ltd concludes that the subject device is substantially equivalent to the predicate devices described herein.