January 12, 2024

Hangzhou IVISTA Medical Devices Co., Ltd.
Yao Cheng
General Manager
No. 7, Chunjiang Road, Qiaonan Development Zone
Ningwei Town, Xiaoshan District
Hangzhou, Zhejiang 311217
China

Re: K233125
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: November 15, 2023
Received: November 16, 2023

Dear Yao Cheng:

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,

FDA Bobak Shirmohammadi -S

For Michael E. Adjodha, M. ChE., 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

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.

510(k) Number *(if known)*
K233125

Device Name
Zirconia Block

Indications for Use *(Describe)*
Zirconia Blocks are intended for use for the production of artificial teeth in fixed or removable dentures,for jacket facing,veneers.All Blocks are processed through dental laboratories or by dental professionals.

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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K233125
Section 3 510(k) Summary

I 510(k) Submitter

Device Submitter: Hangzhou IVISTA Medical Devices Co., Ltd.
No. 7, Chunjiang Road, Qiaonan Development Zone, Ningwei Town,
Xiaoshan District.Hangzhou City 311217,Zhejiang Province, China

Contact Person: Yao Cheng
General Manager
Phone: 86 13905009803
E-mail: cy2179@163.com

II Device

Trade Name of Device:	Zirconia Block
Regulation Number:	21 CFR 872.6660
Classification Name:	Powder, Porcelain
Product Code:	EIH
Regulatory Class	II
Review Panel	Dental

III Predicate Devices

510k Number	**K192262**
Trade Name of Device:	Dental Zirconia Blocks
Regulation Number:	21 CFR 872.6660
Classification Name:	Powder, Porcelain
Regulatory Class	II
Product Code:	EIH

IV Device Description

Zirconia ceramic block is made of ceramic materials (e.g., zirconium oxide) intended to be used to manufacture a final dental appliance/prosthesis (e.g., removable dentures, for jacket facing, veneers) for patient use. It is used to removable restorations using manual or computer-aided design/computer-aided manufacturing (CAD/CAM) technology. After application, this material cannot be reused for fabrication.

V Indications for use

Zirconia Blocks are intended for use for the production of artificial teeth in fixed or removable dentures,for jacket facing,veneers.All Blocks are processed through dental laboratories or by dental professionals.

VI Technological Characteristics Comparison

VI-1: Comparison of Zirconia Block

Device Characteristic	Subject Device	Predicate Device (K192262)	Discussion
Trade name	Zirconia Block	Dental Zirconia Blocks	N/A
Regulation Number	21 CFR 872.6660	21 CFR 872.6660	Identical
Product Code	EIH	EIH	Identical
Manufacturer	Hangzhou IVISTA Medical Devices Co., Ltd.	ARUMDENTISTRY Co., Ltd.	N/A
Device Classification	Powder, Porcelain	Powder, Porcelain	Identical
Intended Use	Zirconia Blocks are intended for use for the production of artificial teeth in fixed or removable dentures,for jacket facing,veneers.All Blocks are processed through dental laboratories or by dental professionals.	Dental Zirconia Blocks are intended for use for the production of artificial teeth in fixed or removable dentures,for jacket facing,veneers.All Blocks are processed through dental laboratories or by dental professionals.	Identical
Prescription Use	Yes	Yes	Identical
Shapes	Blocks	Blocks, disc	Different Comment 1
Color	White and Colour	White and Colour	same
Chemical Composition (Weight %)	$ZrO_2+HfO_2+Y_2O_3$ ≥99.0 ZrO_2 ＞90 Y_2O_3 ≤9.5 Fe_2O_3 ≤0.5 Er_2O_3 ≤0.5 Other oxide /	White zirconia: $ZrO_2+HfO_2+Y_2O_3$ ≥99.0 Y_2O_3 4.5~6.0 HfO_2 ≤5 Al_2O_3 ≤0.5 Other oxide ≤0.5 Color zirconia: $ZrO_2+HfO_2+Y_2O_3$ ≥98.0 Fe_2O_3 ＜0.3 Pr_2O_3 ＜0.2 Er_2O_3 ＜1 Other oxide ≤0.5	Different Comment 2
Density (presintering)	≥2.75g/cm^3	≥3.0g/cm^3	Different Comment 3
Density (post sintering)	≥6.00g/cm^3	≥6.02g/cm^3	

Device Characteristic	Subject Device	Predicate Device (K192262)	Discussion
Sintering Temperature	1500±100 ℃	1400-1600 ℃	Identical
Flexura strength	≥800Mpa	＞800Mpa	Identical
Solubilit	≤100μg/cm^2	＜100μg/cm^2	Identical
Radioactive	≤ 1.0 Bq / g	uranium-238concentration ≤ 1.0 Bq / g.	Identical
Single Use	Yes	Yes	Identical
Sterile	Non-sterile	Non-sterile	Identical
Performance Test	Including:Appearance Test,Dimension Test,Density Test,Product composition Flexural strength,Linear thermal expansion-coefficient,Chemical solubility Radioactivity of dental of ceramic, thermal Fracture toughness comply with ISO 6872	Including:Appearance Test,Dimension Test,Density Test,Product composition Flexural strength,Linear thermal expansion-coefficient,Chemical solubility Radioactivity of dental of ceramic, thermal Fracture toughness comply with ISO 6872	Identical
Biocompatibility	Comply ISO10993-1:2020	Comply ISO10993-1:2018 FDA Guidance, tests included cytotoxicity, oral mucosa irritation, skin sensitization, pyrogenicity,acute systemic toxicity, subacute toxicity,subchronic systemic toxicity,implantation effect and genotoxicity etc	Different Comment 4

Comment 1

Shapes in the subject device have been used in the predicate deviceThe form of the product is not the same but the composition and intended use are the same. Accordingly, it was concluded that the proposed device is substantially equivalent to the predicate device.

Comment 2

All chemical ingredients in the proposed device have been used in thepredicate device and the reference device. Accordingly, it was concludedthat the proposed device is substantially equivalent in biocompatibility tothe predicate device and the reference device.

Comment 3

The pre sintering mainly affects the hardness of products which reflects theeasy degree of material machining operations. The pre sintering density ofthe proposed device is a little different with the predicated device and thereference device, but it has no obvious effect on the hardness, thisdifference does not affect substantial equivalence.

Comment 4

ISO10993-1:2018 Updated to ISO10993-1:2020, we do biocompatibility according to the latest standard and meet the requirements.

VII Summary of Non-clinical Testing (Bench)

The non-clinical testing for Zirconia Block was performed to demonstrate verification testing in conformance with the acceptance criteria of test methods and recognized consensus standards shown below.

Table VII-1: Performance testing was conducted on the subject device

ID#	Test	Method	Acceptance Criteria	Conclusion
1	**Physical Testing of Dental Glass Ceramics**			**Test results of ten samples**
1.1	Chemical Composition	Y_2O_3+Zr(Hf)O_2>99.5%	Product technical requirements	99.9%,99.9%,99.9%,99.9%,99.9%, 99.9%,99.9%,99.9%,99.9%,99.9%
1.2	Chemical Composition	Y_2O_3+Zr(Hf)O_2>99.5%		912Mpa, 914Mpa, 910Mpa, 912Mpa, 915Mpa, 916Mpa, 906Mpa, 913Mpa, 913Mpa, 916Mpa
1.3	Pre-sintering	≥2.75g/cm^3		3.1 and 6.07g/cm^3, 3.1 and 6.06g/ cm^3, 3.1 and 6.06g/cm^3, 3.1 and 6.07g/cm^3, 3.1 and 6.06g/cm^3, 3.1 and 6.07g/cm^3, 3.1 and 6.06g/cm^3, 3.11 and 6.07g/cm^3, 3.1 and 6.06g/cm^3, 3.12 and 6.06g/cm^3
	Post-sintering	≥6.00g/cm^3		
1.4	Sintering Shrinkage Rate	19%-22%		20.53%, 20.51%, 20.49%,20.51%, 20.46%, 20.55%, 20.55%,20.51%, 20.5%, 20.51%

1.5	Pre-sintering	≤2000μg/cm^2		0 and 0μg/cm^2 , 0 and 0μg/cm^2 , 0 and0μg/cm^2 , 0 and 0μg/cm^2 , 0 and 0μg/cm^2, 0 and 0μg/cm^2 , 0 and 0μg/cm^2, 0 and 0μg/cm^2 , 0 and 0μg/cm^2, 0 and 0μg/cm^2
	Post-sintering	≤100μg/cm^2		
1.6	Linear thermal expansion-coefficient	（10.5±0.5）× 10^{-6} K^{-1}		10.5×10^{-6} K^{-1} ,10.6 ×10^{-6} K^{-1} 10.3×10^{-6} K^{-1} ,10.4 ×10^{-6} K^{-1} 10.6×10^{-6} K^{-1} ,10.3 ×10^{-6} K^{-1} 10.5×10^{-6} K^{-1} ,10.4 ×10^{-6} K^{-1} 10.4×10^{-6} K^{-1} ,10.5×10^{-6} K^{-1}
1.7	Scale out rate	The scaling factor falls within the range in between 1.210 and 1.260, and the deviation of the actural value from the nominal value should not be greater than 0.005.		1.245，1.250，1.240，1.242，1.240，1.246，1.240，1.248，1.238，1.249
1.8	Scale out rate	The scaling factor falls within the range in between 1.210 and 1.260, and the deviation of the actural value from the nominal value should not be greater than 0.005.		1.245，1.250，1.240，1.242，1.240，1.246，1.240，1.248，1.238，1.249
1.9	Appearance	Surface: surface should be smooth and pore- free.		Yes, Yes, Yes, Yes, Yes, Yes, Yes, Yes, Yes, Yes
		The color of zirconia porcelain block used for chip processing (initial sintering state) should be uniform, there should be no local pigment separation phenomenon, there should be no foreign body attached.		Yes, Yes, Yes, Yes, Yes, Yes, Yes, Yes, Yes, Yes
		Size: the size error should be less than ± 0.2mm.		+0.03mm, +0.03mm, +0.03mm, +0.02mm, +0.02mm, +0.03mm, +0.02mm, +0.02mm, +0.02mm, +0.02mm

1.10	Packaging	The packing identification should be distinct, and the packing material should not have obvious changes.		No obvious changes, no obvious changes, no obvious changes, no obvious changes, no obvious changes, no obvious changes, no obvious changes, no obvious changes, no obvious changes, no obvious changes
2	**Biocompatibility Testing**			
2.1	Cytotoxicity	ISO 10993-5:2009	Non-Cytotoxicity	Pass
2.2	Sensitization	ISO 10993-10:2021	Non-Sensitization	Pass
2.3	Irritation or intracutaneous reactivity	ISO 10993-23:2021	Non-Irritation or intracutaneous reactivity	Pass
2.4	Acute system ictoxicity	ISO 10993-11:2017	Non-Acute system ictoxicity	Pass
2.5	Subacute toxicity	ISO 10993-11:2017	Non-Subacute toxicity	Pass
2.6	Sub chronic toxicity	ISO 10993-11:2017	Non-Sub chronic toxicity	Pass
2.7	Genotoxicity	ISO 10993-3:2014	Non-Genotoxicity	Pass

VIII Clinical Test Conclusion

No clinical study is included in this submission.

IX Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the Zirconia Block is as safe as effective, and performs as well as or better than the legally marketed device.

X Copy Statement

The Copy is an exact duplicate of the paper copy.

Signature of the applicant: 

date of the submission:2023.12.11