August 30, 2024

Hunan Qinghao Puzhong Technology Co., Ltd.
℅ Yao Xiao
RA Specialist
Beijing Xinranyicheng Medicine & Technology Co., Ltd.
A-1109, Langqin International Building, No.168,
Guang'anmen Outer Street, Xicheng District
Beijing, Beijing 10053
China

Re: K241602
Trade/Device Name: Kingcera Dental Zirconia Blank
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: April 22, 2024
Received: June 4, 2024

Dear Yao Xiao:

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,

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241602

Device Name

Kingcera Dental Zirconia Blank

Indications for Use *(Describe)*

Kingcera Dental Zirconia Blanks are used for dental restorations using different CAD/CAM or manual milling machines. All blanks 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.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

Prepared on: 2024-06-04

Contact Details

K241602

21 CFR 807.92(a)(1)

Applicant Name	Hunan Qinghao Puzhong Technology Co., Ltd.
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Correspondent Contact Telephone	+86-18604590069
Correspondent Contact	Ms. Yao Xiao
Correspondent Contact Email	xinran0057@xinranmed.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Kingcera Dental Zirconia Blank (MT, ST, UT, ET,Standard, Universal, Esthetic)
Common Name	Porcelain powder for clinical use
Classification Name	Powder, Porcelain
Regulation Number	872.6660
Product Code(s)	EIH

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K141724	Upcera Dental Zirconia Blank & Dental Zirconia Pre-Shaded Blan	EIH

Device Description Summary

21 CFR 807.92(a)(4)

Kingcera Dental Zirconia Blanks are derived from zirconia powder that has been processed through various molding and sintering techniques - into their final net shapes. These blanks are further fabricated into various all-ceramic restorations such as crowns, bridges, veneers, and inlay/onlay. The zirconia powder is composed of ZrO2, HfO2, Y2O3, and other oxides; the performance of the Kingcera Dental Zirconia Blanks conforms to ISO 6872-2015, Dentistry: Ceramic Materials. Kingcera Dental Zirconia Blanks are ceramic dental blanks designed to manufacture ceramic dental prosthetic devices. The dental prosthetic devices are fabricated by CAD/CAM machining processes. All prosthetic dental devices are intended for single-use applications. At the dental lab, the blanks are held to t. Kingcera Dental Zirconia Blanks are supplied in different shapes, such as blocks, discs, rods, or customized shapes. They are provided in combinations of ninety-nine different colors and a gradual-changing translucency effect. The different colors originate from the different constituents of color additives (such as Fe2O3 and Er2O3); the different translucencies originate from a slight difference in the amount of Y2O3.

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

Kingcera Dental Zirconia Blanks are used for dental restorations using different CAD/CAM or manual milling machines. All blanks are processed through dental laboratories or by dental professionals.

Indications for Use Comparison 21 CFR 807.92(a)(5)

Kingcera Dental Zirconia Blank has the same indications for use as the predicate device.

Technological Comparison 21 CFR 807.92(a)(6)

The information provided in this subject device is the equivalence of indication for use, material, Flexural Strength, and Chemical Solubility with the predicate device (K141724).Both devices used the same technology for CAD. The performance data demonstrates the proposed device performs as safely and effectively as the predicate device according to ISO 6872. All of our Zirconia Blank are biocompatible according to ISO 10993-1. Therefore, the differences raise no new questions of safety and effectiveness.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Performance testing has been carried out to demonstrate that this device meets the performance specifications for its intended use. The following tests were performed on the device.

- ISO 6872 Fourth edition 2015-06-01 [including AMENDMENT 1 2018-04] Dentistry - Ceramic materials

Not Applicable

No animal studies or clinical testing have been required for these devices.