July 17, 2026

Hunan Qinghao Puzhong Technology Co., Ltd.
℅ Yuqing Yang
RA specialist
Beijing Xinranyicheng Medicine & Technology Co., Ltd.
2-801-01, Floor 7, Bldg. 1, #168 Guanganmenwai St., Xicheng District, Beijing
Beijing, Beijing 10053
CHINA

Re: K261046
Trade/Device Name: Dental Zirconia Blank & Coloring Liquid
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: July 13, 2026
Received: July 14, 2026

Dear Yuqing Yang:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

MICHAEL E. ADJODHA -S

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

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.

510(k) Number *(if known)*
K261046

Device Name
Dental Zirconia Blank & Coloring Liquid

Indications for Use *(Describe)*
Dental Zirconia Blank & Coloring Liquid are used for dental restorations using different CAD/CAM or manual milling machines. All blanks are processed through dental laboratories or by dental professionals. The Coloring Liquid is used for coloring pre-sintered zirconia structures.

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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I. GENERAL INFORMATION K261046

Applicant:

Hunan Qinghaopuzhong Technology Co., Ltd.

1-3F, Building 2.2-F, Xinma Power Innovation Park, No.899 Xianyue Ring Road, Majiahe Street, Tianyuan District, Zhuzhou City, Hunan Province, 412007, China

Zip code:412000

Zhiquan Wang

Phone:86 - 731 - 28700818

E-Mail:www.matovix.com

Contact Person:

Yang YuQing

Phone:+86-18603302976

E-Mail:xinran152@xinranmed.com

Date Prepared: July 9,2026

II. DEVICE INFORMATION

510(K) Number: K261046

Trade Name: Dental Zirconia Blank & Coloring liquid

Common Name : Porcelain Powder for Clinical Use

Classification Name: Porcelain Powder for Clinical Use

Regulation Number: 21 CFR 872.6660

Regulatory Class: Class II

Product Code: EIH

Classification Panel :Dental

Type of 510(k) submission: Traditional

PREDICATE DEVICE INFORMATION

Primary Predicate Device :

510(K) Number:K141724

Trade Name:Upcera Dental Zirconia Blank & Dental Zirconia Pre-Shaded Blank

Submitter/Manufacturer:Liaoning Upcera Company Limited

Reference Device：

510(K) Number: K141723

Trade Name:Upcera Coloring Liquid

Submitter/Manufacturer:Liaoning Upcera Company Limited

III. DEVICE DESCRIPTION

Dental Zirconia Blank 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 ZrO_2, HfO_2, Y_2O_3, and other oxides; the performance of the Dental Zirconia Blanks and the colored Dental Zirconia Blanks using Coloring Liquid conform to ISO 6872-2024, Dentistry: Ceramic Materials. The Coloring Liquid is used for coloring pre-sintered zirconia structures.

Dental Zirconia Blank are ceramic dental blanks designed to manufacture ceramic dental prosthetic devices. These devices are fabricated using CAD/CAM machining processes. All prosthetic dental devices are intended for single-use applications. At the dental lab, the blanks are held to the CAD/CAM machine, which is used to machine the final dental restoration. After the machining steps, the dental restoration is fired (i.e., sintered) in the oven to harden the ZrO_2 to achieve its final properties.

Dental Zirconia Blank are supplied in different shapes, such as blocks, discs or customized shapes. They are provided in combinations of ninety-nine different colors and a gradual-changing translucency effect. The different shades originate from the different constituents of color additives (such as Fe_2O_3 and Er_2O_3); the different translucencies originate from a slight difference in the amount of Y_2O_3. Additionally, The white Dental Zirconia Blanks in models MT, ST, UT, and ET can be colored to different shades with corresponding liquids LMT, LST, LUT, and LET.

IV. INDICATIONS FOR USE

Dental Zirconia Blank & Coloring Liquid are used for dental restorations using different CAD/CAM or manual milling machines. All blanks are processed through dental laboratories or by dental professionals.The Coloring Liquid is used for coloring pre-sintered zirconia structures.

V. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE DEVICE

The following table shows similarities and differences in use, design, and material between the subject Device and the predicate devices(Upcera Dental Zirconia Blank & Dental Zirconia Pre-Shaded Blank[K141724] and Upcera Coloring Liquid[K141723]).

Description	Subject Device	Primary Predicate Device	Reference Device	Comparison
510K Number	K261046	K141724	K141723	-
Product Code	EIH	EIH	EIH	Same
Proprietary Name	Dental Zirconia Blank & Coloring liquid	Upcera Dental Zirconia Blank & Dental Zirconia Pre-Shaded Blank	Upcera Coloring Liquid	-
Manufacturer	Hunan Qinghaopuzhong Technology Co., Ltd.	Liaoning Upcera Company Limited	Liaoning Upcera Company Limited	-
Indications for use	Dental Zirconia Blank & Coloring Liquid are used for dental restorations using different CAD/CAM or manual milling machines.All blanks are processed through dental laboratories or by dental professionals. The Coloring Liquid is used for coloring pre-sintered zirconia structures.	Upcera Dental Zirconia Blanks & Dental Zirconia Pre-Shaded 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.	Upcera Coloring Liquid (l and ll) is a liquid used for the complete or partial coloration of milled Upcera zirconia substructure and anatomy before sintering.	Same: The subject device includes both dental zirconia blank and coloring liquid. The intended use of each constituent is the same as that of its corresponding predicate device.
Basic Design	Blocks and disc	Blocks,disc, and rod	/	Same

Materials	Dental Zirconia Blank	Zirconia(ZrO_2+Y_2O_3+HfO_2 ＞99.0%) Inorganic pigments*≤ 1.0wt%	Regular: Zirconia(ZrO_2+Y_2O_3+HfO_2+Al_2O_3 ≥99.0%) Pre-Shaded: Zirconia(ZrO_2+Y_2O_3+HfO_2+Al_2O_3 ≥98.0%) Inorganic pigments(Fe_2O_3,Pr_2O_3 and Er_2O_3）<2.0%	/	Equivalent[1]
	Coloring Liquid	Water, Polyethylene glycol, inorganic salts	/	Upcera Coloring Liquid I: Water, Polyethylene glycol, HCl, inorganic salts Upcera Coloring Liquid II: Water, Polydextrose, inorganic salts	Equivalent[2]
Processing	Dental Zirconia Blank	Sintering at temperature >1500℃	Sintering at temperature >1500℃	/	Same
Dimension	Dental Zirconia Blank	Various	Various	/	Same
Single Use		Yes	Yes	Yes	Same
Shade	Dental Zirconia Blank	Ninety nine colors and gradual changing translucencies effect.	None,and Pre-shaded(for pre-shaded series)	/	Equivalent: There are Slightly different colors, but it doen’t raise different questions of safety and

					effectiveness than the predicate device.
	Coloring Liquid	Various	/	Various	Same
Sterile		Non-sterile	Non-sterile	Non-sterile	Same

*: The Inorganic pigments mentioned in the Subject Device are consistent with the descriptions of Other oxides, which may contain Al_2O_3, Fe_2O_3, Er_2O_3, etc, with the content ≤1wt%.

Our device's indication for use, design, material, and processing are essentially identical to the predicate device. Minor differences pose no safety or effectiveness concerns. The minor differences are as follows:

Note 1: The subject device's Dental Zirconia Blank contains ZrO_2+Y_2O_3+HfO_2 at >99.0%, with other oxides (Al_2O_3, Fe_2O_3, Er_2O_3, etc.) at ⩽1.0wt%. The predicate device(K141724) combines ZrO_2+Y_2O_3+HfO_2+Al_2O_3 at ⩾99.0% (regular) or ⩾98.0% (pre-shaded), with Fe_2O_3, Pr_2O_3, and Er_2O_3 additives. These compositional variations are minor and within industry standards; biocompatibility testing confirms equivalent safety.

Note 2:The subject device's Coloring Liquid is similar to the predicate device(K141723) , the main components are water, ethylene glycol and inorganic salts, and the predicate device also contains acid (HCl), but it is not the main component and will evaporate during sintering, so the lack of this component will not affect the use of the subject device. All the metal nitrates we use have long-term safety characteristics, and we have tested the biocompatibility of the dyed zirconia ceramic final products, and the results show that the subject device will not cause any safety problems.

VI. Summary of Non-Clinical Testing

Performance testing has been carried out to demonstrate that the Dental Zirconia Blanks and the colored Dental Zirconia Blanks using Coloring Liquid meet 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.

All tests were verified to meet acceptance criteria. The subject device's test results on appearance, radioactivity, flexural strength, chemical solubility, linear thermal expansion coefficient, and sintered density are very similar to those of the predicate device. Biocompatibility testing was performed to verify the equivalent safety of the materials used.

According to ISO 10993-1:2018 and ISO 7405:2025, we evaluated and conducted the compatibility test for the proposed device. The following table shows the biocompatibility testing results.

Item	Proposed device	Primary Predicate Device(K141724) Reference Device(K141723)
Cytotoxicity	No cytotoxicity effect. (ISO 10993-5:2009)	No cytotoxicity effect. (ISO 10993-5:2009)
Oral Mucosa Irritation	The test result of oral mucosa irritation showed that the response category of the test article extract in the golden hamster was None (SC) and None (CO). (ISO 10993-23:2021)	Not a primary oral mucosa irritant under the conditions of the study. (ISO 10993-10:2010)
Sensitization	The sample extract showed no significant evidence of causing skin sensitization in the guinea pig. (ISO 10993-10:2021)	Not a sensitizer under the conditions of the study (ISO 10993-10:2010)
Acute Toxicity/Subacute toxic	The test article showed no significant evidence of causing acute systemic toxicity in the mouse. (ISO 10993-11:2017)	No subacute toxic effects observed (ISO 10993-11:2017)
Subchronic Toxicity	No subchronic toxic effects observed (ISO 10993-11:2017)	No subchronic toxic effects observed (ISO 10993-11:2017)

Genotoxicity Toxicity	No genotoxic effects observed. (ISO 10993-3:2014)	No genotoxic effects observed. (ISO 10993-3:2014)
Implantation	No reaction to the subcutaneous tissue in rabbit after implantation of 26 weeks (ISO 10993-6:2016)	-

Note: Testing was performed on ET-W zirconia blanks that were stained with LET-SQ coloring liquid and subjected to final sintering.

VII. Clinical Test Conclusion

No clinical study is included in this submission

VIII. Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the subject device Dental Zirconia Blank & Coloring Liquid performs as well as or better than the legally marketed predicate device K141724 Upcera Dental Zirconia Blank & Dental Zirconia Pre-Shaded Blank (primary predicate device) and K141723 Upcera Coloring Liquid (Reference Device). Dental Zirconia Blank & Coloring Liquid is substantially equivalent to the legally marketed predicate device K141724 Upcera Dental Zirconia Blank & Dental Zirconia Pre-Shaded Blank (primary predicate device) and K141723 Upcera Coloring Liquid (Reference Device).

According to the Federal Food, Drug, and Cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification, the subject device is substantially equivalent to the predicate device.