May 12, 2025

United Zirconia
℅ Tim Torbenson
Owner
T² & Company
1 Baya Street
Rancho Mission Viejo, California 92694

Re: K250393
Trade/Device Name: ZircaGlow & ZircaGlow HT Zirconia
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: February 11, 2025
Received: February 12, 2025

Dear Tim Torbenson:

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,

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.

Submission Number *(if known)*

K250393

Device Name

ZircaGlow & ZircaGlow HT Zirconia

Indications for Use *(Describe)*

1. Indications for Use
ZircaGlow & ZircaGlow HT Zirconia blanks are indicated for use by dental technicians for the production of full contour and substructures restorations up to a full arch

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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Section 5: 510(k) Summary

510(k) Summary for

United Zirconia's ZircaGlow Zirconia

Date Prepared: 02/08/2025

K250393

Submitter/Applicant: United Zirconia

1. *Applicant Contact:*
Kamal Ebeid
United Zirconia
Land Plot No.164-D
Chemical Industries Zone,
North Katameya Road,
Ein Sokhna, Third Settlement
Cairo, Egypt
Phone: +201002444305
Email: kamal_ebeid@dent.asu.edu.eg

2. *510(k) Number: K250393*
Regulation Number: 872.6660 (Product code EIH)

3. *Device Name*

Proprietary Name:	ZircaGlow & ZircaGlow HT Zirconia
Common/Usual Name:	Powder, Porcelain
Classification Name:	Porcelain powder for clinical use

4. *Predicate Device*

The Argen Corporation, ArgenZ HT+ (K190079) (Primary Predicate)

5. *Indications for Use*

ZircaGlow & ZircaGlow HT Zirconia blanks are indicated for use by dental technicians for the production of full contour and substructures restorations up to a full arch.

6. *Device Description and Function*

ZircaGlow & ZircaGlow HT Zirconia are disc and block shaped dental porcelain zirconia oxide blanks that come in various sizes that are used in custom restorations by the dental laboratory. The dental laboratory will further process the blank by milling the blank based upon the anatomically rendering of the patient's teeth (done at the dental office) through "Computer Aided Drafting/ Computer Aided Machining (CAD/CAM). Once the custom rendered blank is milled the product is fully sintered and colored (if required) and fitted to the patient's teeth as a crown, bridge or coping.

7. *Physical and Performance Characteristics Design:*

As described in Section 5.0 Device Description and Function

Material Used:

ZircaGlow & ZircaGlow HT Zirconia blanks are composed of zirconia ceramics (ZrO_2) based on yttria-stabilized tetragonal zirconia (Y-TZP). The material is biocompatible according to ISO 10993-1: 2018 *"Biological Evaluation of medical devices – Part 1: Evaluation and testing within a risk management process"*

Physical Properties:

Tabulated chart of finished product "ZircaGlow Zirconia & ZircaGlow Zirconia HT" blanks (see next page)

ZircaGlow Zirconia

Sintered Density	≥ 6.04 g cm3
Thermal Expansion coefficient (20-500°C) White	10.5 µm/m °C
Thermal Expansion coefficient (20-500°C) Shade A4	10.5 µm/m °C
Thermal Expansion coefficient (20-500°C) Shade C4	10.5 µm/m °C
Bending Strength White	~1138 MPa
Bending Strength Shade A4	~1085 MPa
Bending Strength Shade C4	~1058 MPa
Fracture toughness White	8.5 MPa $\sqrt{}$ m
Fracture toughness Shade A4	8.1 MPa $\sqrt{}$ m
Fracture toughness Shade C4	8.3 MPa $\sqrt{}$ m

ZircaGlow HT Zirconia

Sintered Density	≥ 6.04 g cm3
Thermal Expansion coefficient (20-500°C) White	10.5 µm/m °C
Thermal Expansion coefficient (20-500°C) Shade A4	10.5 µm/m °C
Thermal Expansion coefficient (20-500°C) Shade C4	10.5 µm/m °C
Bending Strength White	~963 MPa
Bending Strength Shade A4	~961 MPa
Bending Strength Shade C4	~956 MPa
Fracture toughness White	8.7 MPa $\sqrt{}$ m
Fracture toughness Shade A4	8.5 MPa $\sqrt{}$ m
Fracture toughness Shade C4	8.4 MPa $\sqrt{}$ m

Chemical Properties:

ZircaGlow Zirconia

Component (chemical composition)	ZircaGlow Zirconia (percentage by wt.)
$ZrO_2 + HfO_2 + Y2O3$	> 99.9
Y_2O_3	5.60
Fe_2O_3	≤0.001
SiO_2	≤0.01
CaO	≤0.007
Na_2O	≤0.004
Chemical solubility White	< 20 µg/cm_2
Chemical solubility Shade A4	< 20 µg/cm_2
Chemical solubility Shade C4	< 20 µg/cm_2
Radioactivity White	≤ 0.1 Bq·g−1 of 238U
Radioactivity A4	≤ 0.1 Bq·g−1 of 238U
Radioactivity C4	≤ 0.1 Bq·g−1 of 238U

ZircaGlow HT Zirconia

Component (chemical composition)	ZircaGlow Zirconia (percentage by wt.)
$ZrO_2 + HfO_2 + Y2O3$	> 99.9
Y_2O_3	7.60
Fe_2O_3	≤0.001
SiO_2	≤0.01
CaO	≤0.007
Na_2O	≤0.004
Chemical solubility White	< 20 µg/cm_2

Chemical solubility Shade A4	< 20 µg/cm2
Chemical solubility Shade C4	< 20 µg/cm2
Radioactivity White	≤ 0.1 Bq·g−1 of 238U
Radioactivity A4	≤ 0.1 Bq·g−1 of 238U
Radioactivity C4	≤ 0.1 Bq·g−1 of 238U

8. Nonclinical Testing

The device functions in a manner consistent with other legally marketed predicate devices with the same intended use. The observed differences between the subject and predicate devices are minor and do not raise new questions of safety or effectiveness.

The performance characteristics, combined with general use and literature on similar yttria-stabilized zirconia materials, support a determination of substantial equivalence to the predicate for use in dental restorations.

ZircaGlow Zirconia & ZircaGlow Zirconia HT blanks comply with ISO 6872:2024, *"Dentistry – Ceramic materials"* and ISO 13356: 2015, "*Implants for surgery, Ceramic materials based on yttria-stabilized tetragonal zirconia (Y-TZP)".*

9. *Clinical Testing*

Clinical tests have not been performed.

10. Substantial Equivalence Discussion

ZircaGlow Zirconia & ZircaGlow Zirconia HT blanks comparison to the predicate device, The Argen Corporation, ArgenZ HT+ (K190079), is based upon similar characteristics such as: intended use, indications, contra-indications, material properties, chemical composition, processing/fabrication and testing to recognized standards and guidelines. ZircaGlow Zirconia & ZircaGlow Zirconia HT blanks utilizes a substantially equivalent composition (ZrO2+HfO2+Y2O3: > 99), which results in a flexural strength of >800MPa and a fracture toughness of >5.0 MPa $\sqrt{}$ m, therefore allowing for a classification of Class 5 in the ISO 6872:2024 standard. Thus the product meets the standards for "Monolithic-ceramic for prostheses involving four or more units or fully covered substructure for prostheses involving four or more units."

The predicate device's Indications for Use provide for "the production of full contour and substructure restorations up to a full arch" and the subject device also meets the standards for this same indication based upon the specification with ISO 6872:2024.

Additionally, while indication for Use statements now note prescription requirements on the form, we have still indicated the device is for use by dental technicians. We have also noted the prescription requirements in the Instructions for Use and on the device labeling. Both the subject device and predicate device are provided in disc shapes of various sizes. The subject and predicate device have similar physical/mechanical properties that meet the requirements of ISO 6872:2024.

ZircaGlow Zirconia & ZircaGlow Zirconia HT blanks Biocompatibility has been assured through the use of the same material composition and the same manufacturing process as the Predicate device.

	ZircaGlow Zirconia & ZircaGlow Zirconia HT	**ArgenZ HT+ Argen/K190079**
Indications for use	ZircaGlow Zirconia & ZircaGlow Zirconia HT blanks are indicated for use by dental technicians for the production of full contour and substructures restorations up to a full arch.	ArgenZ HT+ (high translucent plus) zirconia can be used for the production of full contour and substructures restorations up to a full arch.

Contra- Indications	ZircaGlow Zirconia & ZircaGlow Zirconia HT Zirconia blanks are milled, the dental technician should take appropriate safety methods such as face mask and eye protection when removing the finished dental prostheses from the holder to preclude inhaling dust particles upon removal with power tools. • Insufficient tooth structure reduction.[1] • Insufficient tooth structure for proper adhesion and force distribution. [1] • Insufficient oral hygiene. • Insufficient interproximal space for sufficient joints in bridges. [1] • Known allergies. [1] • Known incompatibilities to product composition. [1] • Heavy discoloration of prepped tooth structure. [1] *[1] as applicable to the finished article installed by the dentist*	There are no specific contra-indications identified.

	ZircaGlow Zirconia & ZircaGlow Zirconia HT	**ArgenZ HT+ Argen/K190079**
Material Composition % wt.	Zirconia Powder: ZrO_2+HfO_2+Y_2O_3: > 99 wt% Inorganic Pigments < 1%	Zirconia Powder: ZrO_2+HfO_2+Y_2O_3: > 99 wt% Inorganic Pigments < 1%

Freedom from extraneous materials per ISO 6872:2024 Section 5.2 active conc. of not more than 1.0 Bq g-1 of Uranium238	<0.01	Not supplied
Blank sizes (mm)	Disc: 98.5 O.D. x 10-30mm	Disc: Sizes not identified.
Sintered Density g/cm3, ISO 13356: 2024 Section 4.1 Req't. of ≥ 6.0	6.07 g/cm^3	6.08 g/cm^3
Coefficient of thermal expansion (CTE) ISO 6872: 2024, No req't.	10.5 µm/m °C	10.3 µm/m °C
Fracture toughness KIC ISO 6872:2024 Annex A; minimum for class 5, 5.0 MPa m$^{1/2}$	>5.0 MPa m1/2	Not supplied
Average Flexural strength per ISO 6872:2024, Limit >800MPa	>800 MPa	1,348 MPa
Chemical solubility per ISO 6872:2024, Limit 100 µg/cm2	<20 µg/cm2	66.11 µg/cm2
Biocompatibility per ISO 10993-1: Part 1 - 'Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process."	Assured through use of same materials and manufacturing processes as legally marketed predicate devices.	*Tested for Cytotoxicity on shaded material, no adverse reactions identified.*

	ZircaGlow Zirconia & ZircaGlow Zirconia HT	**ArgenZ HT+ Argen/K190079**
Manufacturing Process	Composition Material is acquired in powder form. Ceramic blanks are produced by compression. These compressed blanks are then partially sintered (fired) at high temperatures, which is the same manufacturing process used in the industry to fabricate similar devices.	Composition Material is acquired in powder form. Argen HT+ is a pressed Yttria stabilized Zirconia. The raw materials and manufacturing process used in the fabrication of Argen HT+ are similar to the materials and processes used in the industry to fabricate the predicate devices.
Safety and Efficacy of the Device	The device functions in a manner consistent with other legally marketed predicate devices with the same intended use. The observed differences between the subject and predicate devices are minor and do not raise new questions of safety or effectiveness. The performance characteristics, combined with general use and literature on similar yttria-stabilized zirconia materials, support a determination of substantial equivalence to the predicate for use in dental restorations.	Statement Not Supplied

11. Conclusion:

ZircaGlow Zirconia & ZircaGlow Zirconia HT blanks comparison to the predicate device, ArgenZ HT+ (K190079), is based upon similar characteristics such as: intended use, indications, contra-indications, material properties, chemical composition, processing/fabrication and testing to recognized standards and guidelines. United Zirconia has concluded that ZircaGlow Zirconia & ZircaGlow Zirconia HT blanks are substantially equivalent to this legally marketed predicate device.