February 23, 2021

John Von Thaden, Operations Officer
United Dental Resources Corporation
70 Towncenter Drive
University Park, Illinois 60484

Re: K201915
Trade/Device Name: GenesisZr 4Y+ (ST1100) Zirconia
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: October 10, 2020
Received: October 14, 2020

Dear John Thaden:

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 (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 located 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.

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 803) for

devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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, M.ChE.
Assistant Director
DHT1B: Division of Dental 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201915

Device Name

GenesisZr® 4Y+ (ST1100) Zirconia

Indications for Use *(Describe)*

GenesisZr® 4Y+ (ST1100) 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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Section 5:

K201915

510(k) Summary

for

United Dental Resources Corporation

GenesisZr® 4Y+ (ST1100) Zirconia

1. Submitter

Owners Name:	United Dental Resources Corporation
Address:	70 Towncenter Drive University Park, IL 60484
Phone:	(708) 746-5730
Fax:	(888) 503-2190
Contact Person:	John Von Thaden, Operations Officer
Date summary prepared:	January 21, 2020

2. Device Name

Proprietary Name:	GenesisZr® 4Y+ (ST1100) Zirconia
Common/Usual Name:	Powder, Porcelain
Classification Name:	Porcelain powder for clinical use
Product Code:	EIH
Regulation Number:	21 DFR 872.6660
Device Class:	Class II

3. Predicate Device

The Argen Corporation, ArgenZ HT+ (K190079)

4. Indications for Use

GenesisZr® 4Y+ (ST1100) Zirconia blanks are indicated for use by dental technicians for the production of full contour and substructures restorations up to a full arch.

5. Device Description and Function

GenesisZr® 4Y+ (ST1100) 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.

6. Physical and Performance

Characteristics Design:
As described in Section 5.0 above - Device Description and Function

Material Used:

GenesisZr® 4Y+ (ST1100) 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: 2009 *"Biological Evaluation of medical devices – Part 1: Evaluation and testing within a risk management process"*

Physical Properties:

Tabulated chart of finished product "GenesisZr® 4Y+ (ST1100) Zirconia" blanks (see next page)

Sintered Density	≥ 6.07 g/cm^3
Thermal Expansion coefficient (20-500°C)	10.2 µm/m °C
Bending Strength	1,100 MPa
Grain size	0.66 µm
Fracture toughness	>5.0 MPam$^{0.5}$

Chemical Properties:

Component (chemical composition)	GenesisZr® 4Y+ (ST1100) Zirconia (percentage by wt.)
$ZrO_2 + HfO_2 + Y_2O_3 + Al_2O_3$	> 99.0
Al_2O_3	≤ 0.05
SiO_2	≤ 0.01
Fe_2O_3	≤ 0.01
Chemical solubility	< 100 µg/cm$_2$

7. Nonclinical Testing

United Dental Resources Corporation performed a series of tests to assess whether the device is safe and effective to use. Sintered tests coupled with mechanical bench testing confirmed that the device meets specifications including established international standards and guidance documents. Density, bending strength, fracture toughness, chemical solubility and material characterization/ composition of finished product was conducted to confirm that the product is safe and effective, while meeting performance goals established by standards.

GenesisZr® 4Y+ (ST1100) Zirconia blanks comply with ISO 6872:2015, *"Dentistry – Ceramic materials"* and ISO 13356: 2015, "*Implants for surgery, Ceramic materials based on yttria-stabilized tetragonal zirconia (Y-TZP)".*

8. Clinical Testing

Clinical tests have not been performed.

9. Substantial Equivalence Discussion

GenesisZr® 4Y+ (ST1100) Zirconia blank 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. GenesisZr® 4Y+ (ST1100) Zirconia utilizes a substantially equivalent composition (ZrO_2+HfO_2+Y_2O_3: > 99), which results in a flexural strength of >1,100MPa and a fracture toughness of >5.0 MPa $m^{0.5}$, therefore allowing for a classification of Class 5 in the ISO 6872:2015 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 6872:2015, Section 4 and Annex A.

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 (Section 13) and on the device labeling (Section 13). 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 6872:2015.

GenesisZr® 4Y+ (ST1100) Zirconia Biocompatibility has been assured through the use of the same material composition and the same manufacturing process as the Predicate device.

	GenesisZr® 4Y+ (ST1100) Zirconia	**ArgenZ HT+ Argen/K190079**
Indications for use	GenesisZr® 4Y+ (ST1100) Zirconia 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	When GenesisZr® 4Y+ (ST1100) 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.

	GenesisZr® 4Y+ (ST1100) Zirconia	**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 6872:2015Section 5.2 active conc. of not more than 1.0 Bq g-1 of Uranium238	<0.03	Not supplied
Blank sizes (mm)	Disc: 98.5 O.D. x 10-30mm	Disc: Sizes not identified.
Sintered Density g/cm3, ISO 13356: 2015 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: 2015, No req't.	10.2 µm/m °C	10.3 µm/m °C
Fracture toughness KIC ISO 6872:2015 Annex A; minimum for class 5, 5.0 MPa $m^{1/2}$	>5.0 MPa m1/2	Not supplied
Average Flexural strength per ISO 6872:2015, Limit >800MPa	1,100 MPa	1,348 MPa
Chemical solubility per ISO 6872:2015, Limit 100 µg/cm2	8.229 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.*

	GenesisZr® 4Y+ (ST1100) Zirconia	**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 similar manner to other comparative devices and the intended use is the same. The differences between comparative devices are minor and do not raise new safety concerns. The effectiveness and suitability of the device for the intended purpose is assured through wide, general use of similar other predicate devices that demonstrate the safe use of the device to construct dental restorations.	Statement Not Supplied

10. Conclusion:

GenesisZr® 4Y+ (ST1100) Zirconia blank 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 Dental Resources has concluded that GenesisZr® 4Y+ (ST1100) Zirconia blanks are substantially equivalent to this legally marketed predicate device.