January 28, 2021

United Dental Resources Corporation
John Thaden
Operation Officer
70 Towncenter Drive
University Park, Illinois 60417

Re: K201608
Trade/Device Name: GenesisZr UHT700 Zirconia
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain powder for clinical use
Regulatory Class: Class II
Product Code: EIH
Dated: January 21, 2021
Received: January 25, 2021

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)*

K201608

Device Name

GenesisZr UHT700 Zirconia

Indications for Use *(Describe)*

GenesisZr UHT700 Zirconia blanks are indicated for Monolithic-ceramic for single-unit anterior or posterior prostheses and for three-unit prostheses not involving molar restoration, adhesively, or non-adhesively cemented. Also indicated for fully covered substructure for single-unit anterior or posterior prostheses and for three-unit prostheses not involving molar restoration, adhesively, or non-adhesively cemented.

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.

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Section 5:

K201608

510(k) Summary

for

United Dental Resources Corporation

GenesisZr® UHT700 Zirconia

1. Submitter

Owners Name:	United Dental Resources Corporation
Address:	70 Towncenter Drive University Park, IL 60484
Phone: Fax:	(708) 746-5730 (888) 503-2190
Contact Person:	John Von Thaden, Operations Officer
Date summary prepared:	January 21, 2021

2. Device Name

Proprietary Name:	GenesisZr® UHT700 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

CCRI, Inc., Pavati® Z40.2 (K160867)

4. Indications for Use

GenesisZr® UHT700 Zirconia blanks are indicated for Monolithic-ceramic for single-unit anterior or posterior prostheses and for three-unit prostheses not involving molar restoration, adhesively, or non-adhesively cemented. Also indicated for fully covered substructure for single-unit anterior or posterior prostheses and for three-unit prostheses not involving molar restoration, adhesively, or non-adhesively cemented.

5. Device Description and Function

GenesisZr® UHT700 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.

6. Physical and Performance Characteristics

Design:
As described in Section 5.0 Device Description and Function

Material Used:
GenesisZr® UHT700 Zirconia blanks are composed of zirconia ceramics (ZrO2) 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 "GenesisZr® UHT700 Zirconia" blanks

Sintered Density	≥ 6.04 g cm_3
Thermal Expansion coefficient (20-500°C)	10.2 µm/m °C
Bending Strength	> 600 MPa
Grain size	0.66 µm
Fracture toughness	2.4 $MPam_{0.5}$

Chemical Properties:

Component (chemical composition)	**GenesisZr® UHT700 Zirconia (percentage by wt.)**
$ZrO_2 + HfO_2 + Y2O3 + Al_2O_3$	> 99.9
Y_2O_3	9.85% ±0.65
Al_2O_3	≤ 0.01
SiO_2	≤ 0.02
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 as safe and effective as the predicate device. 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 were conducted to confirm that the product is substantially equivalent in safety and effectiveness, while meeting performance goals established by standards.
GenesisZr® UHT700 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® UHT700 Zirconia blank comparison to the predicate device, CCRI, Inc., Pavati® Z40.2 (K160867), 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® UHT700 Zirconia utilizes an identical composition which results in an identical flexural strength of >600MPa and a fracture toughness of 2.4 MPa m0.5, therefore limiting the device to 3-unit bridges based on the ISO 6872 standard. This has been noted in our Indications for Use. It should also be noted that the predicate device has the same contraindications for 3-unit prostheses involving molars, but the contraindication is in the directions for use for the predicate and we have opted to include it in the Indications for Use for the subject device for increased clarity. Additionally, since Indication for Use statements now note prescription requirements on the form, that has not been included in our Indications for Use statement. It is noted 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 disc size variation of the GenesisZr® UHT700 Zirconia blanks are minor and do not affect substantial equivalence.

The subject and predicate device have similar physical/mechanical properties that meet the requirements of ISO 6872:2015.

GenesisZr® UHT700 Zirconia Biocompatibility has been assured through the use of the exact same material composition and the exact same manufacturing process as the Predicate device.

	GenesisZr® UHT700 Zirconia	**Pavati® Z40.2 (K160867)**
Indications for use	GenesisZr UHT700 Zirconia blanks are indicated for Monolithic-ceramic for single-unit anterior or posterior prostheses and for three-unit prostheses not involving molar restoration, adhesively, or non-adhesively cemented. Also indicated for fully covered substructure for single-unit anterior or posterior prostheses and for three-unit prostheses not involving molar restoration, adhesively, or non-adhesively cemented.	Pavati® Z40.2 Zirconia blanks are indicated for use in prosthetic dentistry to create porcelain (ceramic) prostheses (crowns) in the anterior/ posterior applications. Pavati™ Zirconia blanks are intended to be milled and fully sintered by Dental Professional or Dental Laboratory before use. Pavati™ Zirconia blanks are for "Rx only" and not for use by the general public or sold as “Over-the- Counter”.
Contra- Indications	Class 4 & 5 indications cannot be made with this device. When GenesisZr® UHT700 Zirconia blanks are milled, do not inhale dust when removing dental prosthesis from dental holder. Take appropriate safety methods such as face mask and eye protection.	The Device is contraindicated for dental restorations greater than 3-units in length (per ISO 6872:2015 and the same as reference device #1) The device is contraindicated for 3 unit prostheses involving molar restorations (per ISO 6872:2015). Class 4 & 5 indications cannot be made with this device.
Material Composition % wt. According to ISO 13356:2015 Sec. 3, Table 1	Zirconia Powder: $ZrO_2+HfO_2+Y_2O_3+Al_2O_3$: > 99.9 HfO_2: ≤ 5.0 Y_2O_3: 9.85% ±0.65 Al_2O_3: ≤ 0.1 SiO_2: ≤ 0.02 Fe_2O_3: ≤ 0.01	Zirconia Powder: $ZrO_2+HfO_2+Y_2O_3+Al_2O_3$: > 99.9 HfO_2: ≤ 5.0 Y_2O_3: 9.85% ±0.65 Al_2O_3: ≤ 0.1 SiO_2: ≤ 0.02 Fe_2O_3: ≤ 0.01
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.	Composition Material is acquired in powder form. Ceramic blanks are produced by compression. These compressed blanks are then partially sintered (fired) at high temperatures.

	GenesisZr® UHT700 Zirconia	**Pavati® Z40.2 (K160867)**
Freedom from extraneous materials per ISO 6872:2015 Section 5.2 active conc. of not more than 1.0 Bq g^{-1} of $Uranium_{238}$	<0.03	Meets ISO Standard
Sintered Density g/cm_3 ISO 13356: 2015 Section 4.1 Req't. of ≥ 6.0	6.04 g/cm_3	≥ 6.00 g /cm3
Coefficient of thermal expansion (CTE)	10.2 µm/m °C	10.3 µm/m °C
Fracture toughness K_{IC}	2.4 MPa m0.5	>2.0 MPam0.5
Flexural strength per ISO 6872:2015, Limit >900MPa	600 MPa	Meets ISO Standard
Chemical solubility per ISO 6872:2015 Limit 100 µg/cm2	Meets ISO Standard	< 100 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 the exact same materials and manufacturing methods as legally marketed predicate devices	Biocompatible and Non-toxic Assured through use of same materials and manufacturing methods as legally marketed predicate devices.
Blank sizes(mm)	Disc: 95-110mm x 10-30mm	Block: 65-85 x 40 x 15 20-55 x 19 x 15 40 x 15 x 15 14 x 13 x 15 18 x 14.5 x 12.4 Near net shapes Disc: 95-110 x 12-30

10. Conclusion:

GenesisZr® UHT700 Zirconia blank comparison to the predicate device, CCRI, Inc., Pavati® Z40.2 (K160867), 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. As such, United Dental Resources has concluded that GenesisZr® UHT700 Zirconia blanks are substantially equivalent to this legally marketed predicate device.