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

January 25, 2019

Re: K182642
Trade/Device Name: GenesisZr™ 4Y Zirconia
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: October 22, 2018
Received: October 29, 2018

Dear John Von 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mary S. Runner -S3

Digitally signed by Mary S. Runner -S3
Date: 2019.01.25 15:04:53 -05'00'

For Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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)*
K182642

Device Name
GenesisZr™ 4Y Zirconia

Indications for Use *(Describe)*
GenesisZr™ 4Y Zirconia blanks are indicated for use in prosthetic dentistry to create porcelain (ceramic) prostheses (dentures, crowns and bridges). GenesisZr™ 4Y Zirconia blanks are intended to be milled and fully sintered before use for:

- Full contour monolithic crowns and bridges in anterior and posterior regions.
- Anatomically reduced for veneering, crown and bridge frames.
- Bridge to be limited to 3 units with a maximum of 1 pontic.

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

K182642

for

United Dental Resources Corporation

GenesisZr™ 4Y Zirconia

1. Submitter

Owner's Name:	United Dental Resources Corporation
Address:	70 Towncenter Drive University Park, IL USA 60484
Phone:	1-708-746-5730
Fax number:	1-888-503-2190
Contact Person:	John Von Thaden, Operations
Date summary prepared:	January 25, 2019

2. Device Name and Classification

Proprietary/Trade Name:	GenesisZr™ 4Y Zirconia
Common/Usual Name:	Powder, Porcelain
Classification Name:	Porcelain Powder for Clinical Use
Product Code:	EIH
Regulation Number:	21 CFR 872.6660
Device Class:	Class II

3. Predicate Device

Glidewell Laboratories, Prismatik™ Clinical Zirconia (Prismatik™ CZ) (K060104)

4. Indications for Use

GenesisZr™ 4Y Zirconia blanks are indicated for use in prosthetic dentistry to create porcelain (ceramic) prostheses (dentures, crowns and bridges). GenesisZr™ 4Y Zirconia blanks are intended to be milled and fully sintered before use for:

- Full contour monolithic crowns and bridges in anterior and posterior regions.
- Anatomically reduced for veneering, crown and bridge frames.
- Bridge to be limited to 3 units with a maximum of 1 pontic.

5. Device Description and Function

GenesisZr™ 4Y Zirconia are disc shaped dental porcelain zirconia oxide blanks that come in one color, white, and various sizes that are used in customized 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 customized rendered blank is milled the device is fully sintered and colored (if required) and fitted to the patient's teeth as dentures, crowns or bridges.

6. Substantial Equivalence Discussion

	GenesisZr™ 4Y Zirconia	**Prismatik™ CZ Glidewell/K060104**
Indications for use	GenesisZr™ 4Y Zirconia blanks are indicated for use in prosthetic dentistry to create porcelain (ceramic) prostheses (dentures, crowns and bridges). GenesisZr™ 4Y Zirconia blanks are intended to be milled and fully sintered before use for: - Full contour monolithic crowns and bridges in anterior and posterior regions. - Anatomically reduced for veneering, crown and bridge frames. - Bridge to be limited to 3 units with a maximum of 1 pontic.	For use in prosthetic dentistry to create porcelain (ceramic) protheses. For use only by or on the order of a dental professional such as a DDS or DMD. Not for use by the general public or OTC.
Contra-Indications	Class 5 indications cannot be made with this device. When GenesisZr™ 4Y 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.	There are no specific precautions, warnings or contra-indications

	GenesisZr™ 4Y Zirconia	**Prismatik™ CZ Glidewell/K060104**
Material Composition % wt.	Zirconia Powder: $ZrO_2+HfO_2+Y_2O_3$: >99 Y_2O_3: 6.9 Al_2O_3: ≤ 0.05 SiO_2: ≤0.002 Fe_2O_3: ≤0.002	Zirconia Powder: $ZrO_2+HfO_2+Y_2O_3$: > 99 HfO_2: < 2 Y_2O_3: 5.2 Al_2O_3: ≤ 0.05 Other oxides: < 0.3
Freedom from extraneous materials per ISO 6872:2008 Section 5.2 active conc. of not more than 1.0 Bq g^{-1} of Uranium^{238}	<0.03	N/A
Sintered Density g/cm^3 ISO 13356: 2008 Section 4.1 Req't. of ≥ 6.0	6.09 g/cm^3	N/A
Coefficient of thermal expansion (CTE)	10.2 µm/m °C	N/A
Fracture toughness K_{IC}	3.5 MPa m$^{0.5}$	N/A
Flexural strength per ISO 6872: 2008, Limit >900MPa	1100 MPa	1100MPa
Chemical solubility per ISO 6872:2008 Limit 100 µg/cm^2	6.0 µg/cm^2	N/A
Biocompatibility per ISO 10993-1: Part 1 - 'Biological evaluation of medical devices –Part 1: Evaluation and testing within a risk management process."	Biocompatibility risk management analysis was conducted per ISO 10993-1 of the materials and manufacturing methods to legally marketed predicate devices.	N/A
Blank sizes(mm)	Disc: 95-110mm x 10-30mm	Disc sizes 98.5 x 10-30mm

GenesisZr™ 4Y Zirconia blank comparison to the predicate device, Glidewell Prismatik™ Clinical Zirconia (Prismatik™ CZ) (K060104), 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™ utilizes a greater composition of Y_2O_3 which is added for extra translucency, but results in a fracture toughness of 3.5 MPa $m^{0.5}$, therefore limiting the device to 3-unit bridges based on the ISO 6872 standard. This has been noted in our Indications for Use. However, this difference due to the addition of a specification in the Indications for Use does not affect substantial equivalence. 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 shape of various sizes. The disc size of the GenesisZr™ Zirconia blanks are minor and do not affect substantial equivalence. The subject and predicate device have similar physical/mechanical properties that met the requirements of ISO 6872.

7. Nonclinical Testing

United Dental Resources Corporation performed a series of tests. 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 while meeting performance goals established by standards. GenesisZr™ 4Y Zirconia blanks comply with ISO 6872:2008, *"Dentistry – Ceramic materials"* and ISO 13356: 2008, "*Implants for surgery, Ceramic materials based on yttria-stabilized tetragonal zirconia (Y-TZP)".* A risk management evaluation was done in which the materials, manufacturing processes and use were evaluated per the FDA Guidance, Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" issued on June 16, 2016.

8. Clinical Testing

Clinical tests have not been performed.

9. Conclusion: GenesisZr™ 4Y Zirconia blank comparison to the predicate device, Glidewell Prismatik™ Clinical Zirconia (Prismatik™ CZ) (K060104), 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 believes that GenesisZr™ 4Y Zirconia blanks are substantially equivalent to legally marketed predicate devices.