DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

September 12, 2016

Ccri, Inc.
Robin Carden
President
1319 Calle Avanzado
San Clemente, California 92673

Re: K160867
Trade/Device Name: Pavati Z40.2 Zirconia
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: August 10, 2016
Received: August 11, 2016

Dear Robin Carden:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith, M.S.
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160867

Device Name
Pavati® Z40.2

Indications for Use *(Describe)*
Pavati® Z40.2 Zirconia blanks are indicated for use in prosthetic dentistry to create porcelain (ceramic) prostheses (crowns and bridges) in the anterior/ posterior applications.

Pavati® Zirconia blanks are intended to be milled and fully sintered by Dental Professional or Dental Laboratory before use.

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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510(k) Summary

for CCRI, Inc.

Pavati® Z40.2 Zirconia

1. Submitter

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President
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Secondary Contact Person:

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RA/QA Consultant
Telephone: (949) 413-7189

Date prepared: 21 March 2016

Date revised: 07 September 2016

2. Device Name

Proprietary Name:	Pavati® Z40.2 Zirconia
Common/Usual Name:	Powder, Porcelain
Classification Name:	Porcelain powder for clinical use
Submission Number:	K160867
Regulation Number:	21 CFR872.6600
Product Code:	EIH
Device Classification:	Class II

3. Predicate Devices

- Prismatik Dentalcraft BruxZir Anterior Milling Blanks-K150872 (Primary Predicate)
- Prismatik Dentalcraft BruxZir Anterior-K143330 (Reference Predicate)

4. Indications for Use

Pavati® Z40.2 Zirconia blanks are indicated for use in prosthetic dentistry to create porcelain (ceramic) prostheses (crowns and bridges) in the anterior/ posterior applications.

Pavati® Z40.2 Zirconia blanks are intended to be milled and fully sintered by Dental Professional or Dental Laboratory before use. Pavati® Z40.2 Zirconia blanks are for "Rx only" and not for use by the general public or sold as “Over- the-Counter”.

5. Device Description and Function

Pavati® Z40.2 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 patients 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 patients teeth as crowns or bridges.

6. Physical and Performance Characteristics

Design:

Design considerations included using current dental technology materials (Zirconium oxide) and the same manufacturing processes used throughout the world in fabrication of dental porcelain ceramic blanks. In this submission CCRI, Inc. has combined two similar products, the Prismatik Dentalcraft BruxZir Anterior Milling Blanks-K150872 (Primary Predicate) and the Prismatik Dentalcraft BruxZir Anterior-K143330 (Reference Predicate)

The Zirconia powder is acquired by an approved supplier who is a leader in production of dental ceramic material. This supplier’s material is also used by many dental companies in their own formulations. Zirconia ceramic material was chosen based upon its many years of use in dental restorations by dentists, which when used is chemically/biologically practically inert.

Pavati® Z40.2 Zirconia ceramic blanks are produced by using ZrO_2 powder which is combined with an organic binder (which is burnt-off during firing) and compressed into various configurations. The compressed blanks are then partially sintered (fired) at high temperatures, tested and packaged. These blanks are then sold to Dental labs or dental professionals with the capability to mill the blanks (typically using CAD/CAM techniques) into a final shape (dental restoration) and fully sintered and

colored (if required) before patient installation.

Material Used:

Pavati® Z40.2 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: *"Biological Evaluation of medical devices – Part 1: Evaluation and testing within a risk management process".*

Physical Properties:

Tabulated chart of finished product "Pavati® Z40.2 Zirconia" blanks

Sintered Density	≥ 6.00 g cm^3
Thermal Expansion coefficient (20-500°C)	10.3 µm/m °C
Bending Strength	> 600 MPa
Grain size	0.81 µm
Fracture toughness	>2.0 $MPam^{0.5}$

Chemical Properties:

Component (chemical composition)	Pavati® Z40.2 Zirconia **(percentage by wt.)**
$ZrO_2 + HfO_2 + Y2O_3 + Al_2O_3$	> 99.9
Y_2O_3	9.85% ± .65
Al_2O_3	≤0.1
SiO_2	≤0.02
Fe_2O_3	≤0.01
Chemical solubility	< 100 µg/cm^2

Performance standards used:

ISO 6872:2015, "Dentistry – Ceramic Materials"
ISO 13356:2015 "Implants for surgery, Ceramic materials based on yttria-stabilized tetragonal zirconia (Y-TZP)".
ISO 10993-1: "Biological evaluation of medical devices –Part 1: Evaluation and testing within a risk management process."

7. Nonclinical Testing

CCRI performed a series of tests to assess the 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 was conducted to confirm that the product is meeting performance goals established by standards. Pavati® 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. Comparison to predicate devices (Table below)

Pavati® Z40.2 Zirconia dental porcelain zirconium oxide blanks for use by dental professionals to construct custom dental restorations are substantially similar to the Prismatik Dentalcraft's BruxZir Anterior product lines.

All product testing by CCRI has been done on full sintered product to assure the end user that the performance specifications of the product comply with established consensus standards and are similar to the conditions of ceramic manufacture as the predicate devices.

Both the subject device and the primary predicate device state they are indicate for use by dental professionals. Both the subject device and the primary predicate device are to be used to create prosthesis in the anterior or posterior. ISO 6872:2015 was used to support changes in the technological characteristics in the subject devices vs. the primary predicate device.

Deliverables	Prismatik Dentalcraft BruxZir Anterior Milling Blanks-K150872 (Primary Predicate)	Prismatik Dentalcraft BruxZir Anterior-K143330 (Reference Predicate)	Pavati® Z40.2 Zirconia (Proposed Device)
Indications for Use	The device is indicated for use by dental technicians in the construction of custom made all ceramic restorations for anterior and posterior locations.	The device is indicated for use by dental technicians in the construction of custom made all ceramic restorations for anterior and posterior locations.	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.
Contraindications	This device is contraindicated for dental restorations greater than 3-units in length.	There are no specific contraindications.	The Device is contraindicated for dental restorations greater than 3-units in lengtl (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)
Technical Data and Performance Testing			
Material Composition (wt%) **ZrO_2+HfO_2+Y_2O_3 ≥ 99.0 HfO_2: ≤ 5 Y_2O_3: 9.85% ± .65 Al_2O_3: ≤ 0.5**	Zirconia Powder	Zirconia Powder	Zirconia Powder

Deliverables	Prismatik Dentalcraft BruxZir Anterior Milling Blanks-K150872 (Primary Predicate)	Prismatik Dentalcraft BruxZir Anterior-K143330 (Reference Predicate)	Pavati® Z40.2 Zirconia (Proposed Device)
Other oxides: ≤0.5 **According to ISO 13356:2015 Section 3, Table 1**			
Freedom from extraneous materials per ISO 6872:2015 Section 5.2 active conc. of not more than 1.0 Bq g-1 of Uranium238	Not supplied	Not supplied	Meets ISO Standard
Blank sizes (mm)	Not supplied	Not supplied	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
Sintered Density (g/cm^3) **ISO 13356: 2015 Section 3 Table 1 Req't. of ≥ 6.00**	Meets ISO Standard	Meets ISO Standard	Meets ISO Standard

Deliverables	Prismatik Dentalcraft BruxZir Anterior Milling Blanks-K150872 (Primary Predicate)	Prismatik Dentalcraft BruxZir Anterior-K143330 (Reference Predicate)	Pavati® Z40.2 Zirconia (Proposed Device)
g/cm^3			
Coefficient of thermal expansion (CTE) ISO 6872: 2015, No req't. report number	Not supplied	Not supplied	Meets ISO Standard
Fracture toughness K_{IC} ISO 6872:2015 Annex A; minimum for class 3, 2.0 MPa m$^{1/2}$	Not supplied	Not supplied	Meets ISO Standard
Flexural strength per ISO 6872: 2015, Limit >300 MPa	Meets ISO Standard	Meets ISO Standard	Meets ISO Standard
Chemical solubility per ISO 6872:2015 < 100 µg/cm^2	Not supplied	Not supplied	Meets ISO Standard

Deliverables	Prismatik Dentalcraft BruxZir Anterior Milling Blanks-K150872 (Primary Predicate)	Prismatik Dentalcraft BruxZir Anterior-K143330 (Reference Predicate)	Pavati® Z40.2 Zirconia (Proposed Device)
Grain Size determined per ISO 13356:2015 No req't. for grain size	Not supplied	Not supplied	Meets ISO Standard
Amount of monoclinic phase shall be determined using X-ray diffraction methods in accordance with ISO 13356:2015, ≤20%	Not supplied	Not supplied	Meets ISO Standard
Biocompatibility per ISO 10993-1: Part 1 - 'Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process."	Biocompatible and Non-toxic	Biocompatible and Non-toxic	Biocompatible and Non-toxic Assured through use of same materials and manufacturing methods as legally marketed predicate devices.

9. Conclusion

Pavati® Z40.2 Zirconia blank comparison to the predicate devices, the Prismatik Dentalcraft BruxZir Anterior Milling Blanks-K150872 (Primary Predicate) and the Prismatik Dentalcraft BruxZir Anterior-K143330 (Reference Predicate) 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. CCRI, Inc. believes that Pavati® Z40.2 blanks are substantially equivalent to these legally marketed predicate devices.