



Food and Drug Administration
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October 29, 2015

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

Re: K151875
Trade/Device Name: Pavati™ Zirconia
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain powder for clinical use
Regulatory Class: II
Product Code: EIH
Dated: July 30, 2015
Received: August 3, 2015

Dear Ms. 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" (21CFR 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,

 Tina Kiang -
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for 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

Indications for Use

510(k) Number (if known)
K151875

Device Name
Pavati Zirconia

Indications for Use (Describe)

Pavati™ 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. Pavati™ Zirconia blanks are for "Rx only" and not for use by the general public or sold as "Over-the-Counter".

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™ Zirconia**

1. Submitter

CCRI, Inc.

1319 Calle Avanzado

San Clemente, CA 92673

USA

Contact Person: Robin Carden

Telephone: (949) 366-5221

Date prepared: 28JUL2015

2. Device Name

Proprietary Name: Pavati™ Zirconia

Common/Usual Name: Powder, Porcelain

Classification Name: Porcelain powder for clinical use

Submission Number: K151875 product code EIH

3. Predicate Devices

Glidewell Prisma™ Clinical Zirconia (Prisma™ CZ), (K062509) and Sirona inCoris TZI (K123545)

4. Indications for Use

Pavati™ 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. Pavati™ 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™ 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 from two companies. In the inCoris TZI (Primary Device) the blanks are in a block configuration while the Prismatic CZ (Reference Device) is offered in a disc configuration.

The Zirconia powder is acquired by an approved supplier. 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™ Zirconia ceramic blanks are produced by using ZrO₂ (Zirconium oxide) 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™ 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: 2009 *“Biological Evaluation of medical devices – Part 1: Evaluation and testing within a risk management process”*.

Physical Properties:

Tabulated chart of finished product “Pavati™ Zirconia” blanks

Sintered Density	≥ 6.09 g cm ³
Thermal Expansion coefficient (20-500°C)	10.1 μm/m °C
Bending Strength	> 900 MPa
Grain size	0.45 μm
Fracture toughness	5 MPam ^{0.5}

Chemical Properties:

Component (chemical composition)	Pavati™ Zirconia (percentage by wt.)
ZrO ₂ + HfO ₂ + Y ₂ O ₃ + Al ₂ O ₃	> 99.9
Y ₂ O ₃	5.35 – 5.95
Al ₂ O ₃	≤0.1
SiO ₂	≤0.02
Fe ₂ O ₃	≤0.01
Chemical solubility	18.1 μg/cm ²

Performance standards used:

ISO 6872:2008, <i>“Dentistry – Ceramic Materials”</i>
ISO 13356:2008 <i>“Implants for surgery, Ceramic materials based on yttria-stabilized tetragonal zirconia (Y-TZP)”</i> .
ISO 10993-1: 2009 – <i>“Biological evaluation of medical devices –Part 1: Evaluation and testing within a risk management process.”</i>

7. Nonclinical Testing

CCRI performed a series of tests to assess whether the device is compliant 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 equivalent while meeting performance goals established by standards. Pavati™ 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)”*.

8. Clinical Testing

Clinical tests have not been performed.

9. Comparison to predicate devices (Table below)

Pavati™ Zirconia dental porcelain zirconium oxide blanks for use by dental professionals to construct custom dental restorations are substantially similar to the Glidewell Prisma™ CZ and Sirona inCoris TZI in general composition.

The inCoris TZI “Indications for use” are in the final fully sintered form for installation in the patient. While the Prisma™ CZ “Indications for use” are more general in description and the Pavati zirconia blanks are in a partial sintered form in which the dental laboratory finishes the blanks according to CCRI instructions provided in the “Instructions for use”. 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.

	Pavati™ Zirconia CCRI/K151875	inCoris TZI Sirona/K123545 (Primary Device)	Prismatik™ CZ Glidewell/K060104 (Secondary or Reference Device)
Indications for use	<p>Pavati™ Zirconia blanks are indicated for use in prosthetic dentistry to create porcelain (ceramic) prostheses (crowns and bridges). Pavati™ Zirconia blanks are intended to be milled and fully sintered by Dental Professional or Dental Laboratory before use.</p> <p>Pavati™ Zirconia blanks are for "Rx only" and not for use by the general public or sold as "Over-the-Counter".</p>	<p><u>Classic and Speed Sintering:</u> Fully anatomic crowns and bridges in the posterior and anterior tooth region. Bridges with max. two pontics.</p> <p><u>Super speed Sintering:</u> Fully anatomic crowns.</p>	<p>The device is indicated for use by dental technicians in the construction of custom made all ceramic restorations for anterior and posterior locations.</p>
Contra-Indications/Warnings	<ul style="list-style-type: none"> • Insufficient tooth structure reduction. • Insufficient tooth structure for proper adhesion and force distribution. • Insufficient oral hygiene. • Insufficient interproximal space for sufficient joints in bridges. • Known allergies. • Known incompatibilities to product composition. 	<p>Insufficient oral hygiene¹ Insufficient prep results¹</p> <p><small>¹ as applicable to the finished article installed by the dentist</small></p>	<p>There are no specific precautions, warnings or contra-indications that are required for the use of the device by the dental professional or patient.</p>

	Pavati™ Zirconia CCRI/K151875	inCoris TZI Sirona/K123545 (Primary Device)	Prismatik™ CZ Glidewell/K060104 (Secondary or Reference Device)
	<ul style="list-style-type: none"> • Heavy discoloration of prepped tooth structure. <p>When Pavati 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.</p>		
Technical Data (performance testing included)			
Material Composition(wt%) ZrO ₂ +HfO ₂ +Y ₂ O ₃ ≥ 99.0 HfO ₂ : ≤ 5 Y ₂ O ₃ : > 4.5 to ≤ 6.0 Al ₂ O ₃ : ≤ 0.5 Other oxides: ≤0.5 According to ISO 13356:2008 Section 3, Table 1	Zirconia Powder 454A: Meets ISO 13356: 2008 for Material composition	Zirconia Powder Meets ISO 13356: 2008 for Material composition	Zirconia Powder Not supplied

	Pavati™ Zirconia CCRI/K151875	inCoris TZI Sirona/K123545 (Primary Device)	Prismatik™ CZ Glidewell/K060104 (Secondary or Reference Device)
Freedom from extraneous materials per ISO 6872:2008 Section 5.2 active conc. of not more than 1.0 Bq g ⁻¹ of Uranium238	Meets ISO Standard	Meets ISO Standard	Not supplied
Blank sizes (mm)	Block: 65-85 x 40 x 15 20-55 x 19 x 15 40 x 15 x 15 14 x 13 x 15 Disc: 95-110 x 12-30	110 x 80 x 10	Disc: 98.5 x 10-30
Sintered Density (g/cm ³) ISO 13356: 2008 Section 4.1 Req't. of ≥ 6.0 g/cm ³	Meets ISO Standard	Meets ISO Standard	Not supplied
Coefficient of thermal expansion (CTE) ISO 6872: 2008, No req't. report number	Meets ISO Standard	Meets ISO Standard	Not supplied
Fracture toughness K _{IC} ISO 6872:2008 Annex A; minimum for class 6, 5.0 MPa m ^{1/2}	Meets ISO Standard	Meets ISO Standard	Not supplied

	Pavati™ Zirconia CCRI/K151875	inCoris TZI Sirona/K123545 (Primary Device)	Prismatik™ CZ Glidewell/K060104 (Secondary or Reference Device)
Flexural strength per ISO 6872:2008, Limit >900MPa	Meets ISO Standard	Meets ISO Standard	Meets ISO Standard
Chemical solubility per ISO 6872:2008 Limit 100 µg/cm ²	Meets ISO Standard	Meets ISO Standard	Not supplied
Grain Size determined per ISO 13356:2008 No req't. for grain size	Meets ISO Standard	Meets ISO Standard	Not supplied
Amount of monoclinic phase shall be determined using X-ray diffraction methods in accordance with ISO 13356:2008, ≤20%	Meets ISO Standard	Meets ISO Standard	Not supplied
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 methods as legally marketed predicate devices.	<i>"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.'"</i>	<i>"The biological safety of the device has been assured through the selection of materials similar in composition to the other products currently on the market which have demonstrated appropriate levels of biocompatibility"</i>

	Pavati™ Zirconia CCRI/K151875	inCoris TZI Sirona/K123545 (Primary Device)	Prismatik™ CZ Glidewell/K060104 (Secondary or Reference Device)
Compliance of the Device	<p>Compliance is assured by adherence to ISO 6872:2008, Dentistry- Ceramic Materials and ISO 13356: 2008, "Implants for surgery, Ceramic materials based on yttria-stabilized tetragonal zirconia (Y-TZP)".</p> <p>Validations and testing performed per Section 18.</p>	<p>Device meet ISO 6872: 2008, "Dentistry -- Ceramic materials" and ISO 13356: 2008, "Implants for surgery, Ceramic materials based on yttria-stabilized tetragonal zirconia (Y-TZP)".</p> <p>Physical and chemical properties are similar.</p>	<p><i>"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."</i></p>

10. Conclusion

Pavati™ Zirconia blank comparison to the predicate devices Glidewell Prismatik™ Clinical Zirconia (Prismatik™ CZ K060104) and Sirona inCoris TZI (K123545) 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™ Zirconia blanks are substantially equivalent to these legally marketed predicate devices.