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

Mrs. Magdalena Geigenberger
CEO
Pritidenta Inc.
1170 Howell Mill Road, Suite 300
Atlanta, Georgia 30318

April 7, 2017

Re: K161025
Trade/Device Name: Priti Multidisc Zro2 High Translucent
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: December 22, 2016
Received: December 27, 2016

Dear Magdalena Geigenberger:

This letter corrects our substantially equivalent letter of February 3, 2017.

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,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161025

Device Name
priti® multidisc Zr02 High Translucent

Indications for Use *(Describe)*
priti®multidisc Zr02 High Translucent are pre-sintered zirconium oxide blanks for use in CNC (Computer Numerical Controls) milling machines to fabricate partial and single anterior and lateral crowns, bridges up to 3 units, inlays, onlays, and veneers for dental prostheses for restoration purposes only.

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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Section 5.0: 510(k) Summary

510(k) Summary

I. SUBMITTER

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as our submitter of the answers to the deficiency list for K 161025/S001 and all further information unless other information will come up.

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Date Prepared: Feb 02, 2017

II. DEVICE

Device Name:	priti®multidisc ZrO_2 High Translucent
Common/Usual Name:	Porcelain Powder for Clinical Use
Classification Name:	Powder, Porcelain
Product Code:	EIH
Class:	II

III. PREDICATE DEVICES

Predicate Device
Luxer Shaded Zirconia, K140070

This predicate device has not been subject to a recall.

Reference Predicate Device
DD cube X^2, K150196

This reference predicate device has not been subject to a recall.

Reference device, own 510(k) submission
priti®multidisc ZrO_2 Translucent and priti®multidisc ZrO_2 Opaque, K100250

This reference predicate device has not been subject to a recall.

IV. DEVICE DESCRIPTION

The priti®multidisc ZrO_2 High Translucent blanks are made of Yttria fully stabilized zirconia (5Y-FSZ Fully Stabilized Zirconia), whereby the increased translucency is due to the higher stabilization of the zirconia base powder with yttrium oxide (Y_2O_3).

The priti®multidisc ZrO_2 High Translucent blanks are provided as round discs with a diameter of 98.5mm, and varying thicknesses along with 16 VITA color shades, and multicolor versions.

We hereby specifically state each shade and color available for the subject device:

VITA shades	Heights (10,12,14,16,18,20,25)[mm]
A1	All
A2	All
A3	All
A3,5	All
A4	All
B1	All
B2	All
B3	All
B4	All
C1	All
C2	All
C3	All
C4	All
D2	All

D3	All
D4	All
White	All
multicolor:	
A light (covers range between A1, A2, A3)	14,18,20,25
B light (includes B1, B2)	14,18,20,25
C light (includes C1, C2)	14,18,20,25
D light (includes D2, D3, D4)	14,18,20,25
A dark (includes A3,5; A4)	14,18,20,25
B dark (includes B3, B4)	14,18,20,25
C dark (includes C3, C4)	14,18,20,25

V. INDICATIONS FOR USE

priti®multidisc ZrO_2 High Translucent are pre-sintered zirconium oxide blanks for use in CNC (Computer Numerical Controls) milling machines to fabricate partial and single anterior and lateral crowns, bridges up to 3 units, inlays, onlays, and veneers for dental prostheses for restoration purposes only.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE AND REFERENCE DEVICES

The priti®multidisc ZrO_2 High Translucent, the primary predicate device, Luxer Shaded Zirconia, the reference predicate device, DD cubeX^2, as well as pritidenta's own reference device priti®multidisc ZrO_2 Translucent and priti®multidisc ZrO_2 Opaque are supplied in a pre-sintered state as discs/blanks of varying thicknesses and are suitable for milling to produce crowns or bridges.

All blank materials are ceramics based upon Yttria stabilized zirconium oxide ($ZrO_2/HfO_2/Y_2O_3$). The priti®multidisc ZrO_2 High Translucent and Luxer Shaded Zirconia Predicate Device are fabricated from TOSOH TZ-Series white, yellow, pink and gray powders or equivalent and include Fe_2O_3, Er_2O_3 and Co_3O_4 to provide the color shading, thereby establishing substantial equivalence for the chemical composition of the subject device.

Change of classes due to change in ISO standard:

The priti®multidisc ZrO_2 High Translucent and the predicate devices have been characterized per ISO 6872:2015 Dentistry – Ceramic materials and have met the requirements for their respective categories per ISO 6872. The priti®multidisc ZrO_2 High Translucent device is a Type II, Class 4 material per ISO 6872:2015 Dentistry – Ceramic materials. The primary predicate device, Luxer Shaded Zirconia, materials are Type II, Class 5 per ISO 6872:2015 Dentistry – Ceramic materials. The reference predicate device, DD

cubeX^2, is also a Type II, Class 4 material per ISO 6872:2008 Dentistry – Ceramic materials as is the priti®multidisc ZrO_2 High Translucent device.
Own reference device priti®multidisc ZrO_2 Translucent and priti®multidisc ZrO_2 Opaque are Type II, class 5 devices per ISO 6872:2015 Dentistry – Ceramic materials.

VII. SUBSTANTIAL EQUIVALENCE DISCUSSION

The following table compares the priti®multidisc ZrO_2 High Translucent device to the Primary Predicate Device Luxer Shaded Zirconia, DD cubeX^2 Reference Predicate and Reference Device priti®multidisc ZrO_2 Translucent and Opaque with respect to intended use and technological characteristics, providing more detailed information regarding the basis for the determination of substantial equivalence.

Table 12-1: Substantial Equivalence Comparison Table – priti®multidisc ZrO_2 High Translucent, Predicate Device Luxer Shaded Zirconia, DD cubeX^2 Reference Predicate and Reference Device priti®multidisc ZrO_2 Translucent and Opaque

Characteristics	**priti®multidisc ZrO_2 High Translucent**	**Luxer Shaded Zirconia K140070 Primary Predicate**	**DD cubeX^2 K150196 Reference Predicate**	**priti®multidisc ZrO_2 Translucent and Opaque Reference device**
510(k) Number	This Submission	K140070	K150196	K100250
Trade name	priti®multidisc ZrO_2 High Translucent	Luxer Shaded Zirconia	DD cubeX^2	priti®multidisc ZrO_2 Translucent
Indications for Use	priti®multidisc ZrO_2 High Translucent are pre-sintered zirconium oxide blanks for use in CNC milling machines to fabricate partial and single anterior and lateral crowns, bridges up to three units, inlays, onlays, and veneers for restoration purposes only.	Luxer Shaded Zirconia blanks are intended for use with CAD/CAM technology to produce all ceramic dental restorations (full contour crowns and bridges) as prescribed by a dentist.	Dental blanks made from DD cubeX^2 are indicated for crowns, multi-unit bridges (up to a maximum of three elements) and inlay bridges. Applications include both, anterior and posterior bridges.	priti®multidisc ZrO_2 Translucent / priti®multidisc ZrO_2 Opaque are pre-sintered zirconium oxide blanks for use in CNC milling machines to fabricate crowns, bridges, inlays, and onlays for restoration purposes only.
Classification Code	21 CFR 872.6660 Product Code: EIH	21 CFR 872.6660 Product Code: EIH	21 CFR 872.6660 Product Code: EIH	21 CFR 872.6660 Product Code: EIH

SUBSTANTIAL EQUIVALENCE BASED UPON INTENDED USE				
User	Dental technicians and dentists	Dental technicians and dentists	Dental technicians and dentists	Dental technicians and dentists
User Environ-ment	Dental laboratories, dental offices	Dental laboratories, dental offices	Dental laboratories, dental offices	Dental laboratories and dental offices
Multi-unit bridges	Up to three units	No limitation	Up to three units	No limitations
SUBSTANTIAL EQUIVALENCE BASED UPON TECNOLOGICAL CHRACTERISTICS				
Blank Configu-ration	Discs	Discs	Discs	Discs
Thick-nesses	10 to 25 mm	12 mm to 20 mm	12 mm to 20 mm	10 to 25 mm
Accesso-ries	None	None	Yes, coloring liquids	None
Colors	White, VITA Shades A to D Multicolor (Combination of VITA shades)	White, VITA Shades A to D Multicolor	White	White, VITA Shades A to D Multicolor (Combination of VITA shades)

VIII. PERFORMANCE DATA

Biocompatibility Testing

Biological testing requirements were evaluated based upon FDA Draft Guidance on the Use of International Standard ISO 10993, “Biological Evaluation of Medical Devices Part 1: Evaluation and Testing” (April 23, 2013). As stated in the FDA guidance document referencing Appendix C - Biocompatibility Flow Chart, biocompatibility requirements were met on the basis that the material used in the priti®multidisc ZrO_2 High Translucent device is the same as in the predicate device with the same manufacturing process, same chemical composition, same body contact for both the subject device and the predicate.

Performance Testing

- Performance testing was conducted in accordance with ISO 6872:2008 Dentistry – Ceramic materials. The priti®multidisc ZrO_2 High Translucent device is classified as a Type II, Class 4 device and met the standard requirements per ISO 6872:2015. We also provided a comparison between ISO 6872:2008 and ISO 6872:2015, effects of changes to materials properties.

General type of testing performed:

- Determination of radioactivity by gamma spectroscopy
- Determination of coefficient of thermal expansion
- Determination of chemical solubility
- Determination of flexural strength
- Determination of fracture resistance
- Freedom from extraneous materials test was conducted via literature based risk estimation.

Sterilization

Due to the status of a semi-finished product as a kind of blank that will be finalized at customers labs, these blanks are shipped not sterile.

IX. CONCLUSIONS

The performance testing conducted demonstrates that the priti®multidisc ZrO_2 High Translucent device is substantially equivalent to the predicate devices.

In comparison to the predicate, using ISO standard 6872 the data from that testing concludes that both materials are fundamentally the same. They both have the same fundamental technology and physical properties (coefficient of thermal expansion, biocompatibility, solubility).

Based on the comparative data, priti®multidisc ZrO_2 High Translucent device is essentially the same as currently marketed devices for the same indication, with similar physical and chemical properties, which supports our claim for substantial equivalence.

The priti®multidisc ZrO_2 High Translucent shows no differences in technological characteristics compared to the predicate devices.

The indications for use of this pritidenta's submission (K161025) are covered by indications for use of pritidenta's previous submission of the own reference devices K100250.

That demonstrates that the priti®multidisc ZrO_2 High Translucent device is substantially equivalent to the own reference devices.