DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Talladium, Inc.
Mr. Edward Harms
President/CEO
27360 West Muirfield Lane
Valencia, California 91355

September 15, 2016

Re: K152023
Trade/Device Name: Luminesse Shaded Zirconia SZ
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: June 7, 2016
Received: June 20, 2016

Dear Mr. Harms:

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,

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 HEALI 1i AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910.0120
Expiration Date: January 31,2017
Se& *PRA Statement below.*

510(k) Number *(if known)*
K152023

Device Name
Luminesse Shaded Zirconia SZ

Indications for Use *(Describe)*
Luminesse Shaded Zirconia SZ blanks/discs are indicated for use with CAD/CAM technology or manual milling machines to produce all-ceramic patient specific dental restorations - full contour crowns and bridges for anterior and posterior location - as prescribed by a dentist.

Type of Use *{Select one or both, as applicable)*

Presaiption Use (Part 21 CFR 801 Subpart D) O Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

Date:	September 13, 2016
Sponsor:	Talladium's Inc. 27360 W. Muirfield Lane, Valencia, CA, 91355 P: (661) 295-0900 F: (661) 295-0895
Contact Person:	Edward R. Harms
Trade Name:	Luminesse Shaded Zirconia SZ
Common Name:	Porcelain Powder for Clinical Use
Device Classification:	Class II
Classification Number:	21 CFR 872.6660
Classification Panel:	Dental
CDHR Product Code:	EIH
Indications for Use:	Luminesse Shaded Zirconia SZ blanks/discs are indicated for use with CAD/CAM technology or manual milling machines to produce all-ceramic patient specific dental restorations - full contour crowns and bridges, for anterior and posterior location - as prescribed by a dentist.
Device Description:	Luminesse Shaded Zirconia SZ are used for full contour zirconia dental restorations utilizing CAD/CAM system for design and manufactured. Once designed and manufactured, Luminesse Shaded Zirconia SZ will undergo sintering. The shaded zirconia products are pre-shaded to meet all 16 VITA® shading guide; hence, no further coloring is necessary post-sintering. Once sintered, Luminesse Shaded Zirconia SZ will exhibit maximum strength for posterior and anterior dental restorations.
Non-clinical Performance:	The functionality of Luminesse Shaded Zirconia SZ and their conformance to design input was assessed based on physical

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performance testing (flexural strength, shading consistency and coefficient of thermal expansion – CTE) in accordance with ISO 6872:2008. In addition, biocompatibility information on cytotoxicity, sensitivity and irritation is based upon a biocompatibility assessment conducted in accordance with ISO 10993-1: Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management. Per ISO 10993-1, Luminesse Shaded Zirconia SZ is considered a permanent contact mucosal membrane surface device. Biocompatibility testing was not performed since identical materials are used in the predicate device with the same type and duration of patient contact. Our device is comprised of identical materials and manufacturing methods as the predicate device and other legally marketed devices and does not introduce any new issues.

Substantial Equivalence: The table below compares key characteristics that provide similarities and differences of the predicate device BruxZir™ Shaded (K130924) and the proposed device, Luminesse Shaded Zirconia SZ. If there are any differences between the predicate and proposed devices, they are with respect marketable disc dimensions and they are manufactured to be used exclusively with Sirona's milling system (Cerec and inLab MC XL milling machines). These differences do not introduce any new issues. Both the proposed device, Luminesse Shaded Zirconia SZ, and the predicate device BruxZir™ Shaded (K130924) consist of general porcelain powder material, have the same indication for use and are made following similar manufacturing methods in the industry.

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Luminesse® Shaded Zirconia and BruxZir™ Shaded Comparison Table

Company	***Talladium Inc.***	**Prismatik DentalCraft, Inc.**
510(k) Number	Luminesse Shaded Zirconia SZ (K152023)	BruxZir™ Shaded (K130924)
Indication for Use	Luminesse Shaded Zirconia SZ blanks/discs are indicated for use with CAD/CAM technology or manual milling machines to produce all-ceramic custom dental restorations - full contour crowns and bridges, for anterior and posterior location - as prescribed by a dentist.	The device is indicated for use by dental technicians in the construction of custom made all ceramic restorations for anterior and posterior location. (While the Indication for Use statement is not identical to that of the proposed device, the difference in wording does not raise any concerns or issues about the use of the proposed device).
Product Information (quantities, types)	Over 50 options in disc and block shapes for different milling systems.	About 25 different options in discs for Sirona's milling system.
Dimensions	Disc: 95 and 98 mm diameter discs per 10mm, 12mm, 14mm, 16mm, 18mm, 22mm, 25mm and 30mm thicknesses. Blocks:	98.5 and 100 mm diameter discs per 12mm, 15mm, 20mm and 25mm thicknesses.

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	For Amann Girrbach (milling system): 89mm x 71mm x (10mm, 12mm, 14mm, 16mm, 18mm, 20mm, 22mm, 25mm); For Custom for Lava 72mm x 42mm x (10mm, 12mm, 14mm, 16mm, 18mm, 20mm, 22mm, 25mm); For Sirona inLab: 15mm x 20mm x (14mm and 19mm); 40mm x 15mm x (14mm and 19mm); 55mm x 19mm x 16mm; 65mm x 25mm x 22mm.	
VITA® Shade	All 16 VITA® shades	All 16 VITA® shades

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Summary of Performance Tests – Talladium Shaded ZR

PERFORMANCE TESTS	Talladium's Shaded ZR (K152023)	BruxZir™ Shaded (K130924) Predicate device	Similarities and Differences
Flexural Strength	Average: > 1,000 MPa ISO 6872 requirements: > 800 MPa	Average: 1000 – 1200 MPa Maximum: 1465 MPa	The flexural strength for both proposed and predicate devices are slightly different, but both meet minimum ISO 6872 requirement by over 30%, minimum. Based on the values, the similarities in flexural strength indicate both devices perform the same.
Coefficient of Thermal Expansion	Average ≈ 10.3 x 10^{-6}/K	Average ≈ 11 x 10^{-6}/K	The difference in the coefficients of thermal expansion between proposed and predicate devices are negligible. The negligible difference in CTEs show they will behave very similarly during CAD/CAM machining.
Vickers Hardness	Average ≈ 52 (H.V.)	Average ≈ 49 (H.V.)	A small difference in Vickers's hardness of 3 is reported based on comparison of average values between predicate and proposed devices.

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			This small difference in Vickers's hardness does not impact performance.
Density	>6.05 g/cm^3 (sintered)	5.90 g/cm^3	Within experimental error, the dimensions between proposed and predicate devices are similar. The minor difference in density does not impact the performance of the proposed device compared to predicate.
Chemical Composition: ZrO_2+HfO_2+Y_2O_3+Al_2O_3	>90%	>90%	The chemical composition with relation to the major chemical makeup are identical between proposed and predicate devices.
Biocompatibility Assessment (per ISO 10993-1) **Cytotoxic (IX MEM extraction**	Biocompatibility tests were not performed. However, a biocompatibility final assessment was performed, in a systematic approach, in accordance with ISO 10993-1. This concludes that the following biocompatibility conclusions can be achieved: Expected to meet requirement.	Bruxzir Shaded was tested for Cytotoxicity, Sensitization and Irritation. The tests show the following results: PASS	Since the proposed device is made of same material (classified as porcelain powder) as the predicate device and have similar manufacturing and type of body contact properties, and, in addition, predicate device manufacturer has performed biocompatibility tests, we concluded using our medical device design validation and verification process (which includes FMEA and scientific and clinical literature review) that the proposed device

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method at 37ºC)			biocompatibility performance is similar to predicate device.
Sensitization (ISO Intracutaneous Study, Extract 0.9% sodium chloride USP solution (SC) and sesame oil, NF (SO))	Expected to meet requirement.	PASS	
Irritation and Skin Sensitization Study, Extract 0.9% sodium chloride USP and sesame oil, NF (SO))	Expected to meet requirement.	PASS	

Conclusion: Based upon the chemical composition, non-clinical performance testing and comparison of technology with the predicate device, the subject device is substantially equivalent to the predicate device, Bruxzir Shaded.