



Food and Drug Administration
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October 21, 2015

Talladium, Inc.
Mr. Luiz Galdino
Regulatory Affairs Specialist
27360 W. Muirfield Lane
Valencia, California, 91355

Re: K150266

Trade/Device Name: Luminesse Anterior Zirconia
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: II
Product Code: EIH
Dated: July 19, 2015
Received: July 24, 2015

Dear Mr. Galdino:

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 -S

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

Section 4: Indications for Use

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

Indications for Use

510(k) Number (if known)

K152066

Device Name

Luminesse Anterior Zirconia

Indications for Use (Describe)

Luminesse Anterior Zirconia 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 location - as prescribed by a dentist.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Section 5– 510(k) SUMMARY

Date: October 14, 2015

Sponsor: Talladium’s Inc.
27360 W. Muirfield Lane, Valencia, CA, 91355
P: (661) 295-0900 F: (661) 295-0895

Primary Contact Person: Edward R. Harms – raqa@talladium.com

Secondary Contact Person: Luiz S. Galdino – luiz@talladium.com

Trade Name: Luminesse Anterior Zirconia

Common Name: Porcelain Powder for Clinical Use

Device Classification: Class II

Classification Number: 21 CFR 872.6660

Classification Panel: Dental

CDHR Product Code: EIH

Device Description: Luminesse Anterior Zirconia are used for full contour Zirconia dental restorations utilizing CAD/CAM system for design and manufactured. Once designed and manufactured, Luminesse Anterior Zirconia will undergo sintering. The anterior Zirconia products are pre-shaded to meet all 16 VITA® shading guide; hence, no further coloring is necessary post-sintering. Once sintered, Luminesse Anterior Zirconia will exhibit maximum strength anterior dental restorations.

Intended Use: Luminesse Anterior Zirconia is intended for use by dental technicians in the construction of anterior and posterior all-ceramic restoration with design and manufacturing aid of CAD/CAM technology.

Indications for Use: Luminesse Anterior Zirconia 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 location - as prescribed by a dentist.

Performance Data: The functionality of Luminesse Anterior Zirconia and their conformance to design input was assessed based on performance testing (flexural strength, shading consistency and coefficient of thermal expansion – CTE).

Determination of Substantial Equivalence: The table below compares key characteristics that provides similarities and substantial equivalence of the predicate device BruxZir™ Anterior (K143330) and the proposed device, Luminesse Anterior Zirconia. It is to the best of our knowledge that the comparison table below demonstrates that the proposed Luminesse Anterior Zirconia is essentially the same as currently marketed devices for the same indications for use, and it validates our claim of substantial equivalence to predicate Class II devices under the classification of porcelain powder for clinical use (21 CFR 872.6660) that have previously been found to be substantially

equivalent. If there are any differences between the predicate and proposed devices, they are insignificant and, therefore, does not introduce any new issues. Both the proposed device, Luminesse Anterior Zirconia, and the predicate device BruxZir™ Anterior (K143330) consist of general porcelain powder material, have the same indication for use and have the same intended use.

Luminesse® Anterior Zirconia and Bruxzir™ Anterior Comparison Table

Company	<i>Talladium Inc.</i>	<i>Prismatik DentalCraft, Inc.</i>
510(k) Number	Luminesse Anterior Zirconia (new submission)	BruxZir™ Anterior (K143330)
Intended Use	Luminesse Anterior Zirconia is intended for use by dental technicians in the construction of anterior and posterior all-ceramic restoration with design and manufacturing aid of CAD/CAM technology.	Intended for production of highly esthetic full-contour Zirconia dental restorations utilizing the CAD/CAM system for design and manufacture.
Indication of Use	Luminesse Anterior Zirconia 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 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.
Product Information (quantities, types)	Over 50 options in discs and blocks	Same
Dimensions	Variety	Variety
VITA® Shade	All 16 shades	All 16 shades
Flexural Strength	622 MPa (average) ISO 6872 requirements for anterior > 600 MPa	Meets ISO 6872 requirements
Coefficient of Thermal Expansion	10.5 x 10 ⁻⁶ /K	11 x 10 ⁻⁶ /K
Density	>6.05 g/cm ³ (sintered)	6.046 g/cm ³

Chemical Composition: $ZrO_2+HfO_2+Y_2O_3+Al_2O_3$	>90%	>90%
Biocompatibility (1) Cytotoxic Tests (Agar diffusion test and filter dissusion test) (2) Short-term systemic toxicity (oral route) (3) Test for irritation and delayed-type hypersensitivity (4) Hemolytic Test (5) Ames mutagenicity test (6) Oral mucous membrane irritation test	(1) 0 level (2) No systemic toxicity (3) No hypersensitivity (4) Hemolysis rate, < 5% (5) Mutagenicity Negative (6) No oral mucous irritation	<p style="text-align: center;">Biocompatible and non-toxic Claims are made by manufacturer.</p>

Conclusion:

From the chart above, the differences between the subject device and the predicate device are primarily due to shapes, dimensions and shading availability. Furthermore, the technical performance data supplied for both the subject device and predicate device are not identical but very similar within the expected specifications for porcelain powder used for dental application. Hence, both subject and predicate device can be considered substantially equivalent.

In summary, a comparison between the predicate and subject devices show that:

- They have the same intended use (as described above);
- Share technological characteristics and;
- Contain biocompatibility similarities.

Regards,



X
Edward R. Harms (President/CEO)