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

June 15, 2015

Talladium, Inc.
Ms. Elina Faskhutdinova
RA/QA Manager
27360 W. Muirfield Lane
Valencia, CA 91355

Re: K143090
Trade/Device Name: Luminesse® Pre-Sintered Zirconia Coloring Liquid
Regulation Number: 21 CFR 872.660
Regulation Name: Porcelain powder for clinical use
Regulatory Class: II
Product Code: EIH
Dated: February 24, 2015
Received: March 17, 2015

Dear Ms. Faskhutdinova:

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

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

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)*
K143090

Device Name
Luminesse Pre-Sintered Zirconia Coloring Liquid

Indications for Use *(Describe)*
Luminesse Pre-Sintered Zirconia Coloring Liquid is a device that can be used as an accessory to zirconium dioxide dental restorative material such as Luminesse ZR blanks to provide individualized tooth (or teeth) shading. It is intended to be used solely by certified dental technicians for fabrication of all ceramic restorations for individual dental patients.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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:	09 June 2015
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® Pre-sintered Zirconia Coloring Liquid
Common Name:	Powder, Porcelain
Device Classification:	Class II
Classification Number:	872.6660
Classification Panel:	Dental Devices
CDHR Product Code:	EIH

Device Description: **Luminesse® Pre-sintered Zirconia Coloring Liquid** is a device that can be used as an accessory to zirconium dioxide dental restorative material such as Luminesse® ZR blanks to provide individualized tooth (or teeth) shading. It is a liquid ceramic aid for complete or partial coloring of all zirconium oxide blanks. Dental restorations are designed and manufactured by a certified dental professional (Technician) using CAD/CAM technology.

Intended Use: The **Luminesse® Pre-Sintered Zirconia Coloring Liquid** is intended to be used by trained dental technicians or on the order of a dental professional. The **Luminesse® Pre-Sintered Zirconia Coloring Liquid** is not for use by the general public or over-the-counter.

Indications for Use: The **Luminesse® Pre-Sintered Zirconia Coloring Liquid** is a device that can be used as an accessory to zirconium dioxide dental restorative material such as Luminesse ZR blanks to provide individualized tooth (or teeth) shading. It is intended to beused solely by certified dental technicians for fabrication of all ceramic restorations for individual dental patients.

Predicate Devices: Upcera Coloring Liquid (I and II)K141723

Performance Data: The materials and fabrication processes used in the manufacture of the subject device are similar to the materials and fabrication processes used in the manufacture of the predicate device since the manufacturing of coloring liquids are widely similar in the industry.
Because material biocompatibility was accepted for the predicate and because there are no significant differences in manufacturing which could affect biocompatibility, additional biocompatibility testing was not supplied in support of this clearance.

Data regarding performance testing was provided. Because similar material makeup is used for both the subject and predicate devices, these performance results support the finding of substantial equivalence. The results include general properties (physical form, odor, color), physical and chemical properties (pH, boiling point, density, specific gravity, solubility).

Technological Characteristics:

The fundamental scientific technology of the Talladium's **Luminesse® Pre-Sintered Zirconia Coloring Liquid** is the same as the previously cleared device shown below, i.e., each of the design features is common to the predicate.

PREDICATE DEVICE CHART COMPARISON

	LUMINESSE® PRE-SINTERED ZIRCONIA COLORING LIQUID		**Upcera Coloring Liquid (I and II)**	
Properties and Information	**Acid-based**	**Water-based**	**Acid-based**	**Water-based**
510(k)	K143090		K141723	
Indication for Use	Liquid ceramic aid for complete or partial coloring of all zirconium oxide blanks intended to be used for all ceramic dental restorations		Liquid ceramic aid for complete or partial coloring of all zirconium oxide blanks intended to be used for all ceramic dental restorations	
Prescription Use	Prescription only		Prescription only	
Target Population	General, mostly adults		General, mostly adults	
Type of Packaging	Liquid container	Liquid container	Liquid container	Liquid container
Method of Manufacture	Batch, at VITA® shade		Batch, at VITA® shade	
Packaging Volume (mL)	100 and 250	100 and 250	100 and 250	
VITA® Shade	16	16	16	
Items in Product Line	50	50	37	
Storage Conditions	6 months at 4°C	3-4 years at 4-10°C	6 months at 4°C	3-4 years at 4-10°C
General Physical Form:	Liquid	Liquid	Liquid	Liquid
Specific Physical Form:	Liquid	Liquid	Liquid	Liquid
Odor:	Yellowish orange	Yellowish orange	Yellowish orange	Yellowish orange
Color:	Characteristic odor	Characteristic odor	Mild Odor	Characteristic odor

pH:	1 - 1.5	6.5-7.2	2	7
Boiling Point:	100°C	100°C	100°C	100°C
Density:	1.03-1.09 g/cm^3	1.05-1.10 g/cm^3	1.12 g/cm^3	1.0 g/cm^3
Specific Gravity:	1.03 - 1.09	1.05-1.10	1.12	1.0
Solubility, in Water:	100%	100%	100%	100%
Sterility	Non-sterile		Non-sterile	

Conclusion:

From the chart above, the differences between the subject device and the predicate device are primarily due to the available items in product lines and slight differences in density/specific gravity. Although the **Luminesse® Pre-Sintered Zirconia Coloring Liquid** and predicate devices are available in different volumes, shades and as water-based (both device under review and predicate) and acid-based (new device only), the differences of both the device and predicate device are not and does not raise new questions of safety and effectiveness of the device. Furthermore, the data supplied for both new and predicate device on physical and mechanical properties demonstrate similarity, albeit unequal results, and are within the expected specifications for zirconia dying liquid materials for dental application. Therefore, the differences observed in the chart above do not raise new questions.

In comparison to the predicate device, **Luminesse® Pre-Sintered Zirconia Coloring Liquid** has:

- The same intended use (as described above) and;
- Technological characteristics which do not raise new questions of safety and effectiveness.

In conclusion, Luminesse Pre-Sintered Zirconia Coloring Liquid is substantially equivalent to the predicate device, Upcera Coloring Liquid (I and II).

Edward R. Harms (President/CEO)

June 9, 2015