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

December 17, 2014

Talladium Incorporated
Mr. Edward Harms
Vice President QA/RA
27360 West Muirfield Lane
Valencia, CA 91326

Re: K140848
Trade/Device Name: Luminesse Porcelain System
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain powder for clinical use
Regulatory Class: II
Product Code: EIH
Dated: September 15, 2014
Received: September 18, 2014

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" (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,

Erin I. Keith -S

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

510(k) Number (if known):

Device Name: Luminesse Porcelain System

Indications for Use:

The Luminesse Porcelain System is dental porcelain material to be used in conjunction with metal, zirconia, or pressable ceramic framework in the construction of crowns and/or bridgework and veneers.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

_____

Concurrence of Center for Devices and Radiological Health (CDRH)

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510(k) Summary

December 15, 2014

Contact: Edward R. Harms, CEO

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General Information	
Trade Name	Luminesse Porcelain
Luminesse Porcelain's Assigned 510k	K140848
Common Name	Porcelain powder for clinical use
Predicate 510(k)	Duceragold Porcelains (K040421), Willi Geller Creation Porcelain (K981490), NobelRondo Dental Ceramic – Zirconia (K043312)
Product Code	EIH
Regulation No.	872.6660 Porcelain Powder for Clinical Use
Classification	Class II
Review Panel	Dental
Manufacturer	Talladium Incorporated
Registration #	2023129
Submission Type	Traditional 510k for a New Device

Device Description:

The Luminesse Porcelain is dental porcelain used by dental technicians to create biocompatible crowns, bridges, and veneers. It consists of three categories: low fusing, high fusing, and zirconia porcelain. The application, indication, and performance is the same for all three categories; therefore, it is a porcelain system. It includes Pressable Ingots, Opaque Pastes, Opaque Powders, Opacious Dentins, Dentins, Incisal Powders, Stains, Incisal Transluscents, Dentin Modifiers, Correction Powder, Glaze Powder, Glaze Liquid, Modeling Liquid, and Opaque Liquid. The dental technician will use various components of the system to create the specific, desired dental prosthetic, for the sole use of individual dental patients. It is for prescription use only.

Intended Use:

The Luminesse Porcelain is intended to be used by trained dental technicians or on the order of a dental professional. The Luminesse Porcelain is not for use by the general public or over-the-counter.

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Indications for Use:

The Luminesse Porcelain is porcelain material to be used in conjunction with metal, zirconia, or pressable ceramic framework in the construction of crowns and/or bridgework and veneers.

Technological Characteristics:

Luminesse Porcelain is used to veneer or press over the appropriate base materials (metal or zirconia). In order to prevent cracking and avoid damage of the restoration due to the thermally-induced stress, the average coefficient of thermal expansion has been adjusted to a coefficient of thermal expansion of the appropriate base materials, which allows fusion to the base materials. This is the main technological characteristic of the dental porcelains in general, and it is shared by the subject device and predicate devices. Bench testing to determine flexural strength, solubility, and glass transition temperature was conducted in accordance with ISO 6872.

Conclusion:

All components found in Luminesse Porcelain have been used in legally marketed devices and were found safe for dental use. It has the same technological characteristics, chemical composition, manufacturing process, and same intended use as the predicate devices. Components of this product have not changed in any way that would adversely affect biocompatibility; therefore, it is determined that no biocompatibility testing is necessary for this product. The Luminesse Porcelain, as designed and manufactured, is as safe and effective as the predicate devices.

PREDICATE DEVICES COMPARISON TABLE - LUMINESSE PORCELAIN PRODUCT SIMILARITIES AND DIFFERENCES

Company Information	US FDA 510(k) Number	Product Name	Indications	Technology	Design/Material Composition
Talladium Incorporated	K140848	Luminesse Porcelain, Low-Fusing	The Luminesse Low-Fusing is porcelain material to be used in conjunction with metal, or pressable ceramic framework in the construction of crowns and/or bridgework and veneers.	TALLADIUM's Luminesse LF (Low Fusing) is a low-fusing glass/leucite ceramic keyed to the *VITA® shade guide. For Porcelain Fused-to-Metal restorations the recommended alloy CTE range for the Luminesse II is 13.8 - 14.4 @ 600 ºC. Luminesse LH can be used on All Ceramic (AC), Pressed-to-Metal (PTM) and Fused-to-Metal Restorations (FTM).	Leucite-fortified glass ceramic provided in powder, liquids and pressable pellets delivery designs.
Talladium Incorporated	K140848	Luminesse Porcelain High-Fusing	The Luminesse High-Fusing is porcelain material to be used in conjunction with metal, or pressable ceramic framework in the construction of crowns and/or bridgework and veneers.	TALLADIUM's Luminesse HF (Low Fusing) is a high-fusing glass/leucite ceramic keyed to the *VITA® shade guide for life-like esthetics. For Porcelain Fused-to-Metal restorations the recommended alloy CTE range for the Luminesse HF is 13.8 – 15.1 @ 600 ºC. Luminesse HF can be used on All Ceramic (AC), Pressed-to-Metal (PTM) and Fused-to-Metal Restorations (FTM). In contrast to Luminesse LF, HF offers a higher tensile strength during cyclical firings and higher translucency.	Leucite-fortified glass ceramic provided in powder, liquids and paste designs.

Talladium Incorporated	K140848	Luminesse Porcelain, Zirconia	The Luminesse Zirconia is porcelain material to be used in conjunction with zirconia framework in the construction of crowns and/or bridgework and veneers.	TALLADIUM's Luminesse ZR is a high feldspathic-content veneering porcelain and an ideal match for all zirconia or lithium disilicate substructures. Its 13.2 average CTE provides suitability to zirconia restorations.	Feldspathic porcelain designed specifically foir zirconia substructure restorations. These are provided in liquid and powder application formats.
Dentsply International	K040421 (Predicate Device)	Duceragold® Porcelains	Preparation of crowns and bridges - veneering metal Framework and copings and veneering pressable ceramic.	Ducera Gold is a low-fusing porcelain used for PFM restorations. At an average CTE of 15.1, it is used successfully on certain metal substrates. **SIMILARITIES**: Geared toward low-fusing CTE metals to prevent cracking; Available in powder and paste; Instructions of use: (1) Tooth/Dye Preparation (2) Waxing (3) Spruing (4) Investing (5) Burnout (6) Pressing (7) Divesting (8) Opaque firing (9) Apply Porcelain (10) Build-up Dentine and Enamel layers (11) A second firing may be used for fine adjustments and account for shrinkage. (12) A final glaze firing is necessary to achieve the ideal shine of the tooth. **DIFFERENCES:** Average CTE for Duceragold is higher; FIring temperature used is higher (800C x 750C); Instructions of use (secod firing is not recommended in Duceragold porcelains).	Duceragold porcelain is a silica based low CTE porcelain offered in the powder and liquid formats for metal-based substructures. Specific material makeup of Duceragold were not publicly available likely due to its proprietary value. **SIMILARITIES:** The application and general basis of the chemistry is substantially equivalent to Luminesse Low-Fusing porcelain; Silica as the main ingredient and pigments are organically based. **DIFFERENCES:** Unless specific chemistry makeup of Duceragold is known, one cannot compare the material composition.

Jensen Industries	K981490 (Predicate Device)	Willi Geller Creation CC Porcelain	Willi Geller Creation porcelain is a dental ceramic that is used by dental technicians to fabricate dental restorations including porcelain fused to metal crowns and bridges, laminate veneers, and inlays.	Creation CC is a high-fusing metal-ceramic with unique optical and physical properties. The perfectly coordinated ceramic materials have excellent homogeneity and thus guarantee high flexural strength. The result: a densely sintered structure for pure and non-porous layering with the utmost reliability. At an average 13.3 CTE, it is suitable to Pressed-to-Metal and Fused-to-Metal restorations. **SIMILARITIES:** Technology created to accomodate suitable metals with higher CTE; Instructions of Use (as described above) are identical. **DIFFERENCES:** Lower CTE than Luminesse HF CTE range; Not available in paste as Luminesse; slight deviation in Instruction of Use, such as firing temperatures.	**Obtained from filed 510(k) Summary:** The ceramic powders in the Creation porcelain system are composed in varying proportions of silicon dioxide, aluminum dioxide, sodium oxide, potassium oxide, tin oxide, barium oxide and iron oxide. Chemically stable mixed metal oxides, including spinel, baddeleyit, zircon, and periclase phases of zirconium, iron, cobalt, chromium, yttrium, cerium, nickel and zinc oxides, are used in trace amounts for pigmentation. The paste opaques are comprised of ceramic powder fitting this description suspended in glycerol, zinc chloride, sodium acetate, propandiol, and aerosol. The stains are composed of silicon dioxide, alumiun oxide, potassium oxide, tin oxide, barium oxide, iron oxide, and calcium oxide, and chemically stable mixed metal oxides for pigmentation. **SIMILARITIES:** Most all oxides are present in both Luminesse High-Fusing and Willi Geller Creation CC porcelain.
Nobel Biocare USA LLC	K043312 (Predicate Device)	NobelRondo Dental Ceramic - Zirconia	NobelRondo Dental Ceramic - Zirconia is a ceramic material intended for veneering substructures such as single crowns, multiple frameworks or abutments made from zirconia.	NobelRondoTM Zirconia offers veneering for zirconia substrates in dental restoration. **SIMILARITIES:** Instruction of use and CTE. **DIFFERENCES:** Language in instruction of use (shoulder x neck, which is used in Luminesse Zirconia),	NobelRondo's Ceramic Zirconia is a silica based ceramic offered in the powder for zirconia substructures' restorations Specific material makeup of NobelRondo Ceramics were not publicly available likely due to its proprietary value. **SIMILARITIES:** The application and general basis of the chemistry is substantially equivalent to Luminesse Zirconia given its spefic applicability to ZIrconia restorations. **DIFFERENCES:** Unless specific chemistry makeup of NobelRondo Ceramics is known, one cannot compare the material composition. However, given NobelRondo's product lineup, some of their fluorescent ceramics have a different pigmentation composition.