CONTINENTAL Dental Laboratories

MAY 07 2014

510(k) Summary

Luxer Shaded Zirconia
K140070

1. **Date of Summary Preparation:** May 6, 2014

2. **Submitting Firm:** Continental Dental Ceramics, Inc.

3. **Contact Person:**

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4. **Name of Medical Device**

Proprietary Name: Luxer Shaded Zirconia

Regulation Name: Porcelain Powder for Clinical Use
Regulation Number: 872.6660
Product Code: EIH
Classification Name: Powder, Porcelain
Classification: Class II
Panel: Dental

5. **Predicate Device:** K112710 – ZENO Zr
Wieland Dental + Technik GmbH & Co. KG

6. **Description of Medical Device:**

Luxer Shaded Zirconia blanks are pressed and sintered blocks of Yttria stabilized Zirconia for use in CAD/CAM milling machines. It comes in different thicknesses (12 mm – 20 mm) and classic VITA shades A-D. In order to achieve pigmentation, four basic color components are used from the TOSOH TZ-Series of zirconia (white, yellow, pink, and gray) that yield corresponding VITA shades (A-D).

After the Zirconia block is milled, it is sintered into a high strength all ceramic material suitable for full contour crowns and bridges. The material is biocompatible, has a high flexural strength (>1100 Mpa), and is water insoluble. These characteristics meet the ISO standard 6872 for an esthetic dental ceramic material.

7. **Intended Use**

Luxer Shaded Zirconia blanks/discs are intended for use with CAD/CAM technology to produce all-ceramic dental restorations (full contour crowns and bridges) as prescribed by a dentist.

8. **Substantial Equivalence**

Continental Dental believes that Luxer Shaded Zirconia blanks are substantially equivalent to other legally marketed devices in the United States, such as K112710 ZENO Zr, Wieland Dental + Technik Gmbh & Co. KG. Both Luxer Shaded blanks and the predicate device are made from porcelain powder (product code EIH) and exhibit similar physical and chemical properties.

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, indications for use, physical properties (flexural strength, biocompatibility, solubility) and other technical similarities.

Based on the comparative data, Luxer Shaded Zirconia is essentially the same as currently marketed devices for the same indication, with similar physical and chemical properties, and supports our claim for substantial equivalence.

9. **Non-Clinical Testing**

Non-clinical testing was performed in order to validate the design against the company's specified design requirements for physical and chemical properties, as well as flexural strength, and to assure conformance with the voluntary design standard ISO 6872:2008. Please see attached Standard Data Report (Form 3654).

10. **Biocompatibility**

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 of safety or effectiveness.

11. **Safety & Effectiveness**

The successful prior use of the components of Luxer Shaded Zirconia product in legally marketed devices, the similarity of the formulations used in this device and earlier devices, and the substantially equivalence of Luxer Shaded Zirconia blanks to prior cleared devices support the safety and effectiveness of this product for the intended use.

It has been shown in this 510(k) submission that the difference between Luxer Shaded Zirconia discs and the predicate device do not raise any questions regarding its safety and effectiveness.

END OF SECTION

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

May 7, 2014

Continental Dental Ceramics, Incorporated
Mr. Jerry Doviack, CDT
President
1873 Western Way
Torrance, CA 90501

Re: K140070
Trade/Device Name: Porcelain Powder for Clinical Use
Regulation Number: 21 CFR 872.6660
Regulation Name: Powder, Porcelain
Regulatory Class: II
Product Code: EIH
Dated: April 30, 2014
Received: May 1, 2014

Dear Mr. Doviack:

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,

Mary S. Runner -S

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K140070

Device Name: Luxer Shaded Zirconia

Range of Indications:

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.

Prescription Use ___X__ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sheena A. Green -S
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