K112710

OCT 17 2011

9 510(k) Summary

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Date of Summary:	09/16/2011
Proprietary name:	ZENO Zr Disc,
Model name:	ZENOTEC Zr Bridge ZENOSTAR Zr Translucent ZENOTEC Color Zr ZENOSTAR Color Zr
Classification name:	Porcelain powder for clinical use
Product code:	EIH
C.D.R section:	872.6660
Classification:	Class II
Legally marketed equivalent device:	Cercon base (K013230) LAVA Frame ; LAVA Frame Shade; LAVA Ceram (K011394)

510 (k) Summary

Device description

ZENO Zr Disc is a group of medical devices, which is intended to fabricate all-ceramic dental restorations like crowns and bridges. It consists of two various materials:

1.) "ZENOTEC Zr Bridge" and "ZENOSTAR Zr Translucent" are discoidal shaped and partially sintered dental ceramic materials that are composed of yttria (yttrium oxide) stabilized zirconium dioxide (Y-TZP). Both models are available in various colors, translucencies and thicknesses.

They are provided as pre-sintered blanks, which are ready to be processed in a milling machine with the CAD/CAM technology to get the desired shape, and has then to be sintered at high temperature to its full density, in order to achieve the well-known, excellent effectiveness and safety of the zirconia.
Sintered ZENO Zr Disc materials are biocompatible, insoluble in water and have extremely high strengths, which makes it possible to manufacture delicate and filigree all-ceramic frameworks and restorations. This, together with the various available colors and translucencies of the zirconia materials, offers the basis for aesthetically pleasing, safe and effective dental restorations.
ZENO Zr Disc meets all applicable requirements of the standard ISO 6872: 2008 "Dentistry – Ceramic materials".

2.) "ZENOTEC Color Zr" and "ZENOSTAR Color Zr" are coloring liquids, which consist of watery, acidic metal salt solutions. They are intended to be used for the individual staining of dental zirconia frameworks and restorations.

They are provided in various shades, respectively, which are corresponding to every tooth color. For staining, the zirconia materials have to be immerged into the liquids (ZENOTEC Color Zr) or to be brushed with the liquids (ZENOSTAR Color Zr), before sintering at high temperatures.

Staining with ZENOTEC Color Zr or ZENOSTAR Color Zr does not have any impact on safety and efficiency of the zirconia, but only match the color of the material.

Indications for use

ZENO Zr Disc is intended to be used by professional dental technicians for fabrication of all-ceramic restorations for the sole use of particular patients. It is recommended for manufacturing single-tooth and bridgework restorations, like crowns and bridges with one or two pontics, which can be used in the anterior as well as in the posterior tooth region.

Substantial equivalence

ZENO Zr Disc equals the predicate device with respect to the indications for use and the fundamental technology, i.e. the material constituents, the application process (CAD/CAM –Technology, the biocompatibility, the chemical solubility and the other technical performances.

For this reason, it can be concluded that ZENO Zr Disc is as safe, as effective and performs as well than the predicate device.

Composition of the ZENO Zr Disc assortment

1. **ZENOTEC Zr Bridge**

ZENOTEC Zr Bridge (white)
ZENOTEC Zr Bridge (Colored)
ZENOTEC Zr Bridge (Translucent)

The discs are provided in thicknesses of 10; 12; 14; 16; 18; 20 and 25 mm

2. **ZENOSTAR Zr Translucent**

ZENOSTAR Zr Translucent (pure)
ZENOSTAR Zr Translucent (light)
ZENOSTAR Zr Translucent (medium)
ZENOSTAR Zr Translucent (intense)

The discs are provided in thicknesses of 10; 12; 14; 16; 18; 20 and 25 mm

3. **ZENOTEC Color Zr**

ZENOTEC Color Zr (A1 – A4; B1 – B4; C1 – C4; D2 – D4)

The coloring liquids are provided in 100 and 250 ml bottles.

4. **ZENOSTAR Color Zr**

ZENOSTAR Color Zr (A1 – A4; B1 – B4; C1 – C4; D2 – D4; brown, orange, grey-violett, white, ivory)

The coloring liquids are provided in 30ml bottles.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Dr. Gerhard Polzer
Director Regulatory Affairs
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Schwenninger Str. 13
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Germany

OCT 17 2011

Re: K112710
Trade/Device Name: ZENO Zr Disc
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: II
Product Code: EIH
Dated: September 16, 2011
Received: September 19, 2011

Dear Dr. Polzer:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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4 Intended Use

"ZENO Zr Disc" is a group of medical devices, which is intended to fabricate all-ceramic dental restorations like crowns and bridges. It consists of ceramic blanks and coloring liquids.

"ZENOTEC Zr Bridge" and "ZENOSTAR Zr translucent" are yttria stabilized zirconium dioxide (Y-TZP) ceramic (zirconia) blanks for the CAD/CAM-production of dental restorations.

"ZENOTEC Color Zr" and "ZENOSTAR Color Zr" are coloring liquids for the shading of white zirconia ceramic materials.

The products are intended to be used by professional dental technicians for fabrication of all-ceramic single tooth and bridgework restorations, with one or two pontics, in the anterior as well as in the posterior tooth region.

The Indications for Use statement can be found in chapter 12.

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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