



Food and Drug Administration
10903 New Hampshire Avenue
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May 20, 2015

Tanaka Dental
c/o Ms. Betsy A. Brown
B.A. Brown & Associates
8944 Tamaroa Terrace
Skokie, Illinois 60076

Re: K140491

Trade/Device Name: Tanaka ZirColor™ Coloring Liquid, Tanaka ZirColor™ Dipping
Liquid and Tanaka Enamel ZR™ Blocks

Regulation Number: 21 CFR 872.6660

Regulation Name: Porcelain Powder for Clinical Use

Regulatory Class: II

Product Code: EIH

Dated: April 25, 2015

Received: April 30, 2015

Dear Ms. Brown:

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,

 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

Indications for Use

510(k) Number (if known) K140491

Device Name: Tanaka ZirColor™ Coloring Liquid, Tanaka ZirColor™ Dipping Liquid and Tanaka Enamel ZR™ Block

Indication for Use:

Tanaka ZirColor™ Coloring Liquid and Tanaka ZirColor™ Dipping Liquid are liquids for the shading of white zirconia ceramic materials. This product is intended to be used by professional dental technicians for fabrication of all-ceramic single tooth crown and bridgework restorations.

Tanaka Enamel ZR™ Blocks are yttria-stabilized tetragonal zirconia polycrystals (Y-TZP) ceramic (zirconia) blanks intended to be used by professional dental technicians for the fabrication of all-ceramic restorations. 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.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR Over-the-Counter Use _____
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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Section 5: Page – 4

510(k) Summary

Tanaka ZirColor™ Coloring Liquid, Tanaka ZirColor™ Dipping Liquid and Tanaka Enamel ZR™ Blocks

ADMINISTRATIVE INFORMATION

510K Summary preparation date: May 15, 2015

Manufacturer Name: Tanaka Dental
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DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name: **Tanaka ZirColor™ Coloring Liquid
Tanaka ZirColor™ Dipping Liquid and
Tanaka Enamel ZR™ Blocks**

Common Name: Porcelain Powder for Clinical Use
21 CFR 872.6660

Product Code: EIH

Classification Panel: Dental Products Panel, Class II

Reviewing Branch: Dental Devices Branch

INTENDED USE:

Tanaka ZirColor™ Coloring Liquid and **Tanaka ZirColor™ Dipping Liquid** are liquids for the shading of white zirconia ceramic materials. This products is intended to be used by dental technicians for fabrication of all-ceramic single tooth crown and bridgework restorations.

Tanaka Enamel ZR™ Blocks are yttria-stabilized tetragonal zirconia polycrystals (Y-TZP) ceramic (zirconia) blanks intended to be used by professional dental technicians for the fabrication of all-ceramic restorations. 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

DEVICE DESCRIPTION:

Tanaka ZirColor™ Coloring Liquid is supplied as twenty different shades (4 ml each) of metallic oxide based liquid used for the shading of white zirconia ceramic materials. The liquid is identified as the following twenty shades: A1, A2, A3, A3.5, A4, B1, B2, B3, B4, Occlusal, C1, C2, C3, C4, D2, D3, D4 Incisal Dk, Incisal Lt and Pink. A liquid thinner agent comprised solely of the base component contained in the Tanaka

ZirColor™ Coloring Liquid (15 ml), and 2 birch wood handle brushes for the application of the coloring agent also are supplied.

Tanaka ZirColor™ Dipping Liquid (50% diluted formulation of the Tanaka ZirColor™ Coloring Liquid) is supplied as sixteen different shades (30 ml each) of metallic oxide based liquid used for the shading of white zirconia ceramic materials. The Tanaka ZirColor™ Dipping Liquid is identified as the following sixteen shades: A1, A2, A3, A3.5, A4, B1, B2, B3, B4, C1, C2, C3, C4, D2, D3, and D4.

Tanaka Enamel ZR™ Blocks are yttria-stabilized zirconium dioxide (Y-TZP) ceramic (zirconia) blanks supplied in the following five shades: neutral, light, medium, dark and body. These shades are achieved by using the different shades of ZirColor™ Liquid noted above. The zirconia blanks are provided as the following ten sizes:

No. 01	98.25 +/- 0.2 mm	10.0+/- 0.1 mm
No. 02	98.25 +/- 0.2 mm	12.0+/- 0.1 mm
No. 03	98.25 +/- 0.2 mm	14.0+/- 0.1 mm
No. 04	98.25 +/- 0.2 mm	16.0+/- 0.1 mm
No. 05	98.25 +/- 0.2 mm	18.0+/- 0.1 mm
No. 06	98.25 +/- 0.2 mm	20.0+/- 0.1 mm
No. 07	98.25 +/- 0.2 mm	22.0+/- 0.1 mm
No. 08	98.25 +/- 0.2 mm	24.0+/- 0.1 mm
No. 09	98.25 +/- 0.2 mm	26.0+/- 0.1 mm
No. 10	98.25 +/- 0.2 mm	29.0+/- 0.1 mm

EQUIVALENCE TO MARKETED DEVICE:

Tanaka ZirColor™ Coloring Liquid and Tanaka ZirColor™ Dipping Liquid are substantially equivalent in intended use, technology and performance to Zenotec Color Zr and Zenostar Color Zr, the predicate product cleared under K112710.

EQUIVALENCE TO MARKETED DEVICE (continued):

Primary Predicate

ZENO Zr Disc (K112710)

Tanaka Enamel ZR™ Blocks are substantially equivalent in intended use, material, technology, design and performance to Zenotec Zr Bridge and Zenostar Zr Translucent, the predicate product also cleared under K112710.

Table 1: Substantial Equivalence Summary

Technological Characteristics	<u>Subject Device</u> Tanaka ZirColor™ Coloring Liquid, Tanaka ZirColor™ Dipping Liquid and Tanaka Enamel ZR™ Block	<u>Primary Predicate</u> Zenotec Color Zr, Zenostar Color Zr and Zenotec Zr Bridge and Zenostar Zr Translucent the predicate product cleared under K#112710
Indication for Use	<p>Tanaka ZirColor™ Coloring Liquid and Tanaka ZirColor™ Dipping Liquid are liquids for the shading of white zirconia ceramic materials. This product is intended to be used by professional dental technicians for fabrication of all-ceramic single tooth crown and bridgework restorations.</p> <p>Tanaka Enamel ZR™ Blocks are yttria-stabilized tetragonal zirconia polycrystals (Y-TZP) ceramic (zirconia) blanks intended to be used by professional dental technicians for the fabrication of all-ceramic restorations. 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.</p>	<p>“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.</p> <p>“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.</p> <p>“ZENOTEC Color Zr” and “ZENOSTAR Color Zr” are coloring liquids for the shading of white zirconia ceramic materials.</p> <p>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.</p>

Table 2: Substantial Equivalence Summary

Technological Characteristics	Subject Device Tanaka ZirColor™ Coloring Liquid and Tanaka ZirColor™ Dipping Liquid	Primary Predicate Zenotec Color Zr and Zenostar Color Zr, the predicate product cleared under K#112710
Material Composition	- metallic oxide solution	- acidic metal salt solution
Performance characteristics	Coloring liquids are provided in various shades which correspond to most tooth colors. For staining, the zirconia materials have to be brushed with the liquids (Tanaka ZirColor™ Coloring Liquid) or to be immersed into the liquids for 10 -30 seconds (Tanaka ZirColor™ Dipping Liquid) before sintering at high temperatures (1450°C – 1500°C for 2 hours). The product has a two year shelf-life and is provided as non-sterile. The product meets ISO 10993: 2009 Part 5 biocompatibility requirements.	“ZENOTEC Color Zr” and ZENOSTAR Color Zr” coloring liquids are provided in various shades which correspond to every tooth color. For staining, the zirconia materials have to be immersed into the liquids (Zenotec Color Zr) or to be brushed with the liquids (Zenostar Color Zr) before sintering at high temperatures (1450°C-1500°C for 2 hours).
Principle of Operation	Tanaka ZirColor™ Coloring Liquid and Tanaka ZirColor™ Dipping Liquid utilizes CAD/CAM technology to produce the dental zirconia restoration and ionic metallic oxides to provide coloring/shading to the zirconia restoration. The coloring formulation is applied to the pre-sintered zirconia restoration using a brush or by dipping. The restoration is then sintered in a dental furnace at a high temperature which causes the base carrier solution to “burn-off” leaving behind trace amounts of ionic metallic oxides that provide the coloring to the zirconia restoration.	Zenotec Color Zr coloring liquid utilizes CAD/CAM technology to produce the dental zirconia restoration and ionic metallic oxides to provide coloring/shading to the zirconia restoration. The coloring formulation is applied to the pre-sintered zirconia restoration using a brush or by dipping. The restoration is then sintered in a dental furnace at a high temperature which causes the base carrier solution to “burn-off” leaving behind trace amounts of ionic metallic oxides that provide the coloring to the zirconia restoration.
Differences	The only difference between the ZirColor™ and the Zenotec products is their base solutions. ZirColor™ is a hydrocarbon base solution.	The only difference between the Zenotec and the Tanaka ZirColor products is their base solutions. Zenotec is a acid/water/alcohol base solution.

Table 3. Substantial Equivalence Summary

Technological Characteristics	<u>Subject Device</u> Tanaka Enamel ZR™ Block	<u>Primary Predicate</u> Zenotec Zr Bridge and Zenostar Zr Translucent predicate product cleared under K112710
Material Composition	- ceramic material, yttria-stabilized tetragonal zirconia polycrystals (Y-TZP)	- ceramic material, yttria (yttrium oxide) stabilized zirconium dioxide (Y-TZP)
Performance Characteristics	Tanaka Enamel ZR™ Blocks are disc shaped and partially sintered dental ceramic materials composed of yttria-stabilized tetragonal zirconia polycrystals (Y-TZP) that meets ISO 6892: 2008, ISO 10993:2009-5, ISO 10993: 2006-10 and ISO 13356: 2008 Standard requirements. The blocks are available in various shades and thicknesses. The blocks are sintered at 1450 ⁰ C-1500 ⁰ C for 2 hours with a heating rate of 3 ⁰ C – 10 ⁰ C/min and a cooling rate of 5 ⁰ - 10 ⁰ C/min.	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) that meets ISO 6872:2008 Standard requirements. Both models are available in various colors, translucencies and thicknesses.
Principle of Operation	Tanaka Enamel ZR™ Blocks utilizes CAD/CAM technology to produce the dental zirconia restoration and ionic metallic oxides to provide coloring/shading to the zirconia restoration. The coloring formulation is applied to the pre-sintered zirconia restoration using a brush or by dipping. The restoration is then sintered in a dental furnace at a high temperature which causes the base carrier solution to “burn-off” leaving behind trace amounts of ionic metallic oxides that provide the coloring to the zirconia restoration.	Zeno Zr Disc utilizes CAD/CAM technology to produce the dental zirconia restoration and ionic metallic oxides to coloring/shading to the zirconia restoration. The coloring formulation is applied to the pre-sintered zirconia restoration using a brush or by dipping. The restoration is then sintered in a dental furnace at a high temperature which causes the base carrier solution to “burn-off” leaving behind trace amounts of ionic metallic oxides that provide the coloring to the zirconia restoration.

Table 3: Substantial Equivalence Summary (continued)

Technological Characteristics	Tanaka Enamel ZR™ Blocks	Zenotec Zr Bridge and Zenostar Zr Translucent predicate product cleared under K112710
Differences	There are no differences between the Tanaka Enamel ZR™ Block and the Zeno Zr Disc. However, their coloring solutions used to shade the zirconia blocks differ in their base solutions. The ZirColor™ is a hydrocarbon base solution.	There are no differences between the Zeno Zr Disc and the Tanaka Enamel ZR™ Block. However, their coloring solutions used to shade the zirconia blocks differ in their base solutions. The Zenotec Coloring liquid is a acid/water/alcohol base solution.

Summary of Non-clinical Testing:

The Tanaka Enamel ZR™ Blocks were tested and found to conform to the ISO 10993 Biocompatibility Standard requirements for Cytotoxicity, Acute Systemic Oral Toxicity, Sensitization and Oral Mucosa Irritation.

Physiochemical testing in accordance with ISO 13356: 2008 Implants for Surgery-Ceramic Materials based on Ytria-Stabilized Tetragonal Zirconia (Y-TZP) and ISO 6872: 2008 Standards for Dental Ceramics was performed on the Tanaka Enamel ZR™ Blocks

The Tanaka ZirColor™ Coloring Liquid and Tanaka ZirColor™ Dipping Liquid were also tested and found to conform to the ISO 10993 Biocompatibility Standard for Cytotoxicity, Acute Systemic Oral Toxicity, Sensitization and Oral Mucosa Irritation.

Real-time shelf-life stability testing was conducted on the Tanaka ZirColor™ Coloring Liquid and Tanaka ZirColor™ Dipping Liquid.

Although the base solutions for the ZirColor™ Coloring and Dipping Liquids and the Zenotec Color Zr and Zenostar Color Liquids are not identical (i.e. hydrocarbon base solution and acid/water/alcohol base solution respectively) the differences do not affect the intended use, performance characteristics, or principle of operation. Testing was conducted to validate the different characteristics and demonstrate that the base solutions allow the metallic oxide particles to adhere to the surface of the zirconia material and provide the desired shading to the tooth structure.

Conclusion for Substantial Equivalence:

Tanaka ZirColor™ Coloring Liquid and Tanaka Zircolor™ Dipping Liquid are substantially equivalent to the predicate products, Zenotec Color Zr and Zenostar Color Zr, which were cleared under K112710.

Also, Tanaka Enamel ZR™ Block is substantially equivalent to the predicate products Zenotec Zr Bridge and Zenostar Zr Translucent, cleared under K112710.