



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - WO66-G609  
Silver Spring, MD 20993-0002

December 16, 2015

Wieland Dental + Technik Gmbh & Co. Kg  
% Donna Hartnett  
Director QA/Regulatory Affairs  
Ivoclar Vivadent, Inc.  
175 Pineview Drive  
Amherst, New York 14228

Re: K152118  
Trade/Device Name: Zenostar MT, Zenostar MT Color Liquids  
Regulation Number: 21 CFR 872.6660  
Regulation Name: Porcelain Powder For Clinical Use  
Regulatory Class: Class II  
Product Code: EIH  
Dated: November 13, 2015  
Received: November 16, 2015

Dear Ms. Donna Hartnett:

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" (21 CFR 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,

A handwritten signature in black ink that reads "Susan Runna DDS, MA". The signature is written in a cursive style. In the background, there is a faint, light-colored watermark logo that appears to be the letters "FDA" in a stylized font.

Erin Keith  
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)  
K152118

Device Name  
ZENOSTAR MT

### Indications for Use (Describe)

Zenostar MT (medium translucency) are machinable zirconium oxide discs for the production of all-ceramic crowns, partial crowns and bridges in the anterior and posterior region.

Zenostar® MT Color Liquids are ready-made, water-based solutions for shading full contour restorations made from Zenostar MT. They are applied prior to sintering using the brush technique.

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  
[PRASStaff@fda.hhs.gov](mailto:PRASStaff@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."*

K152118  
**510(K) SUMMARY**



Contact: Donna Marie Hartnett

Company: Wieland Dental + Technik GMBH & Co KG  
Lindenstrasse 2  
71175 Pforzheim, Germany

Date Prepared: December 15, 2015

Proprietary Name: **Zenostar MT**

Classification Name: Powder, Porcelain (872.6660)  
(Classification Code EIH)

Predicate Device: Primary predicate: IPS e.max CAD/IPS e.max ZirCAD (K051705) by Ivoclar Vivadent, AG (Liechtenstein)  
Reference device: Zenotec Zr Bridge, Zenostar Zr Translucent, Zenotec Color Zr, Zenostar Color Zr, by Wieland Dental (K112710).

Device Description: Zenostar MT are zirconia discs with 98.5mm width and 2 thicknesses, 14 mm and 18 mm, for use in the fabrication of dental prosthesis through the CAD/CAM milling technology. In addition, coloring liquids for shading full-contour restorations made from Zenostar MT.

Indications for Use:

Zenostar MT (medium translucency) are machinable zirconium oxide discs for the production of all-ceramic crowns, partial crowns and bridges in the anterior and posterior region.

Zenostar MT Color Liquids are ready-made, water-based solutions for shading full-contour restorations made from Zenostar MT. They are applied prior to sintering using the brush technique.

Comparison to Predicate: The predicate device to which Zenostar MT has been compared is IPS e.max ZirCAD (K051705) and Zenostar MT Coloring Liquids have been compared to those in the predicate Zenotec Zr Bridge, Zenostar Zr Translucent, Zenotec Color Zr, Zenostar Color Zr, by Wieland Dental (K112710). All the ingredients except three nitrates in the coloring liquids have been used in the predicates. The biocompatibility of the new coloring liquid formulation was fully assessed and found to be equivalent to that of the predicate. For this application, Zenostar MT has been compared to its predicate with regard to chemical composition, performance data and indications for use. The comparison shows that Zenostar MT is substantially equivalent to the predicate device.

**K152118**  
**510(K) SUMMARY**



A MEMBER OF THE IVOCCLAR VIVADENT GROUP

<b>Device Name</b>	<b>Zenostar MT K152118</b>	<b>Primary Predicate IPS e.max CAD/IPS e.max ZirCAD K051705</b>	<b>Reference Device Zenotec Zr Bridge, Zenostar Zr Translucent, Zenotec Color Zr, Zenostar Color Zr K112710</b>
<b>Manufacturer</b>	Weiland Dental + Technik GmbH & Co. KG	Ivoclar Vivadent, AG	Weiland Dental + Technik GmbH & Co. KG
<b>510K Number</b>	K152118	K051705	K112710
<b>Product Code</b>	<b>EIH</b>	<b>EIH</b>	<b>EIH</b>
<b>Indications for Use</b>	<p>Zenostar MT (medium translucency) are machinable zirconium oxide discs for the production of all-ceramic crowns, partial crowns and bridges in the anterior and posterior region.</p> <p>Zenostar MT Color Liquids are ready-made, water-based solutions for shading full-contour restorations made from Zenostar MT. They are applied prior to sintering using the brush technique.</p>	<p>IPS e.max CAD is a CAD/CAM machinable glass ceramic based on lithium disilicate for the preparation of full ceramic crowns, inlays, onlays and full ceramic 3-unit anterior bridges.</p> <p>IPS e.max ZirCAD consists of machinable zirconia blocks for the preparation of full ceramic crowns, onlays and 3- and 4-unit bridges and inlay bridges (anterior and molar).</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. 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 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>
<b>Contraindicated Use of Device</b>	<p>Zenostar MT</p> <ul style="list-style-type: none"> <li>- Bridge restorations with more than 3 units</li> <li>- Very deep sub-gingival preparations</li> <li>- Patients with substantially reduced residual dentition</li> <li>- Bruxism</li> <li>- Extended bridges</li> <li>- Any other use not listed in the indications</li> <li>- Temporary insertion</li> </ul>	<p>IPS e.max CAD</p> <ul style="list-style-type: none"> <li>- Full veneers on molar crowns</li> <li>- Very deep sub-gingival preparations</li> <li>- Patients with substantially reduced residual dentition</li> <li>- bruxism</li> <li>- any other use not listed in the indications</li> </ul> <p>IPS e.max ZirCAD</p> <ul style="list-style-type: none"> <li>- More than two joined pontics</li> </ul>	N/A

K152118  
510(K) SUMMARY

	Zenostar MT Color Liquids  All applications which are not listed in the labeling are considered as contraindications.	<ul style="list-style-type: none"> <li>- Very deep sub gingival preparations</li> <li>- Patients with substantially reduced residual dentition</li> <li>- Bruxism</li> </ul> <p>Any other use not listed in the labeling</p>	
<b>Delivery Forms</b>	98.5mm discs  Coloring Liquids packaged in bottles	Machinable blocks in various sizes with attached mandrel to fit milling machine	98.5 mm discs  Zenostar Color Zr liquids packaged in bottles
<b>Design Parameters</b>			
<b>Minimum Wall Thickness</b>	Zenostar MT for 3 unit anterior bridges: Minimum wall thickness 1.2mm  Zenostar MT for 3 unit posterior bridges: Minimum wall thickness 1.5mm	IPS e.max CAD for 3 unit anterior bridges: Minimum wall thickness circular 1.2mm Minimum wall thickness incisal/occlusal 1.5mm staining technique, 0.8mm cut-back technique  IPS e.max ZirCAD for 3 unit posterior bridges: Minimum framework dimension circular 0.5mm Minimum wall thickness occlusal 0.7mm	N/A
<b>Minimum Connector Dimension</b>	Anterior Bridges: Minimum Connector dimension 12mm <sup>2</sup>  Posterior Bridges Minimum Connector dimension 16mm <sup>2</sup>	IPS e.max CAD: Minimum Connector dimension 16mm <sup>2</sup>  IPS e.max ZirCAD: Minimum Connector dimension 9mm <sup>2</sup>	N/A
<b>Classification</b>	Type II Class 5	IPS e.max CAD: Type II Class 3/3  IPS e.max ZirCAD: Type II Class 6	N/A
<b>Biocompatibility</b>	ISO 10993 and ISO 7405	ISO 10993 and ISO 7405	N/A
<b>CAD/CAM Processing</b>	Yes	Yes	Yes
<b>Physical Properties</b>			
<b>Flexural Strength</b>	>550 MPa	IPS e.max CAD: >360 MPa  IPS e.max ZirCAD >900 MPa	N/A

K152118  
**510(K) SUMMARY**



A MEMBER OF THE IVOCAR VIVADENT GROUP

Mechanical Testing	ISO 6872:2008	ISO 6872:2008	ISO 6872:2008
Sterile	No	No	No
Reusable	No	No	No
Principles of Operation	<p>Zenostar MT milling discs are supplied in a partly sintered state. They are processed in the Wieland Zenotec milling machine using dry machining. Final sintering takes place after milling in a compatible sintering furnace. The Ivoclar Vivadent Programat S1 sintering furnace or the Wieland Zenotec System sintering furnace are recommended.</p> <p>Prior to sintering the Zenostar MT restorations can be infiltrated with Zenostar MT Color Liquids using the brush technique to achieve individual shades.</p> <p>The dental restoration can be conventionally cemented using either phosphate cement or glass ionomer cement or adhesively using a composite based adhesive. Ivoclar Vivadent recommends using Multilink® Automix for adhesive cementation, SpeedCEM® for self-adhesive cementation and Vivaglass®CEM PL for conventional cementation.</p>	<p>IPS e.max CAD: Pre-crystallized blocks ready to be processed in a compatible CAD/CAM milling machine.</p> <p>IPS e.max ZirCAD Blocks are supplied in a partly-sintered state. They are processed in a compatible milling machine using wet machining. Final sintering takes place after milling in a compatible sintering furnace. The Ivoclar Vivadent Programat S1 sintering furnace is recommended.</p> <p>The dental restoration can be conventionally cemented using either phosphate cement or glass ionomer cement or adhesively using a composite-based adhesive.</p>	<p>Zenostar Zr Translucent are partly-sintered zirconium milling discs processed using dry machining. Final sintering takes place after milling.</p> <p>Zenostar Color Zr liquids are used prior to sintering to infiltrate the zirconia restorations using the brush technique to achieve individual shades.</p>

The predicate includes IPS e.max CAD which is a silicate-based dental ceramic and IPS e.max ZirCAD which is zirconium oxide. Zenostar MT is zirconium oxide. The composition of the zirconium materials is very similar. IPS e.max ZirCAD and Zenostar MT do not contain pigments. It is possible to achieve esthetic restorations with IPS e.max ZirCAD by veneering them using IPS e.max Ceram. To achieve aesthetic restorations with Zenostar MT the milled restoration is infiltrated with Zenostar MT Color Liquids before sintering. Zenostar MT Color liquids are ready-made, water-based solutions for shading full-contour restorations made from Zenostar MT. The shades are as follows: A1, A2, A3, A3.5, A4, B1, B2, B3, B4, C1, C2, C3, C4, D2, D3, D4,

**K152118**  
**510(K) SUMMARY**



A MEMBER OF THE IVOCCLAR VIVADENT GROUP

Testing Summary: The device has been designed and tested in accordance with ISO 6872:2008 Dentistry: Ceramic Materials for Flexural Strength, Chemical Solubility, Co-efficient of thermal expansion and Radioactivity. The product-specific standard ISO 6872:2008 specifies for a Class 5 material for three-unit prostheses involving molar restoration a minimum mean flexural strength of 500 MPa. Zenostar MT fulfills these criteria. The test results are equivalent to those of the predicate device. Zenostar

MT, Zenostar MT Color Liquids have been thoroughly assessed for biocompatibility in accordance with EN ISO 10993-1:2009 Biological assessment of medical devices, EN ISO 7405:2008 Dentistry – Evaluation of biocompatibility of medical devices used in dentistry, and EN ISO 14971:2012 “Medical devices – Application of risk management to medical devices. The biocompatibility is substantially equivalent to the predicate devices.

CONCLUSION: The indications, design parameters and physical properties of Zenostar MT lie between those of IPS e. max CAD and IPS e. max ZirCAD. Zenostar MT also includes Zenostar MT Color liquids which are applied to the milled restoration prior to sintering to achieve individual shades. This technique is already used as shown in the cleared Zenostar Zr Translucent predicate.

The above data and analysis demonstrates that Zenostar MT is substantially equivalent to the predicate device.