



Food and Drug Administration
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October 29, 2015

Ivoclar Vivadent AG
c/o Ms. Donna Hartnett
Director QA/Regulatory Affairs
Ivoclar Vivadent, Inc.
175 Pineview Drive
Amherst, New York 14228

Re: K151894

Trade/Device Name: IPS Ivocolor
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain powder for clinical use
Regulatory Class: II
Product Code: EIH
Dated: September 18, 2015
Received: September 21, 2015

Dear Ms. 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" (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,

 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)

K151894

Device Name

IPS IVOCOLOR

Indications for Use (Describe)

Staining and/or characterization and glazing of ceramic materials from Ivoclar Vivadent and Wieland Dental:

- Veneering ceramics
- Press ceramics
- Milling ceramics
- Zirconium oxide (frameworks and full-contour restorations)

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.

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510(K) SUMMARY

Revised
IPS Ivocolor



Contact: Donna Marie Hartnett

Company: Ivoclar Vivadent, AG
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+423-235-3535

Date Prepared: October 27, 2015

Proprietary Name: IPS Ivocolor

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

Predicate Device: IPS 99 One and IPS 99 Ceram (K121359) (primary)
Eris Layering Materials (K012174) (reference only)

Device Description: IPS Ivocolor is a universal stains and glaze assortment consisting of 23 shades of Essence porcelain, 9 shades of Dentin porcelain, 3 incisal porcelains, 2 Glaze powders, 2 glaze pasts, 2 Mixing Liquids, Essence fluid and shade guides. The range of products has been coordinated with the layering, press and CAD Ceramics from Ivoclar Vivadent and the zirconium oxides from Wieland Dental and be used regardless of the CTE of the ceramic. The difference is that IPS Ivocolor can be used with both metal-ceramic and full-ceramic materials.

Indications for Use:

Staining and/or characterization and glazing of ceramic materials from Ivoclar Vivadent and Wieland Dental:

- Veneering ceramics
- Press ceramics
- Milling ceramics
- Zirconium oxide (frameworks and full-contour restorations)

Comparison to Predicate: The primary predicate devices to which IPS Ivocolor has been compared are IPS 99 One and IPS 99 Ceram (K121359). Eris Layering Materials (K012174) have also been used as a reference. Ivocolor's indication for individualized staining, characterization and glaze of ceramic materials is the same as IPS 99 shades, stains and glaze. For this application, IPS Ivocolor has been compared to its primary predicate with regard to the chemical compositions, physical properties, operating principals and indications for use. The comparison shows that IPS Ivocolor is substantially equivalent to the primary predicate device.

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Indications for Use	Predicate device IPS 99 Ceram (K121359)	IPS Ivocolor
Indications	<p>The IPS 99 system contains shades, stains and glaze materials used for the characterization of metal ceramic restorations.</p> <p>In addition: IPS 99 Ceram is a conventional multi-layer veneering ceramic for the fabrication of metal-ceramic restorations using the most popular dental alloys in the CTE range of $13.8-15.0 \times 10^{-6}/K$ (25-500°C). IPS 99 One is a one-layer veneering ceramic for the fabrication of metal-ceramic restorations using the most popular dental alloys in the CTE range of $13.8-15.0 \times 10^{-6}/K$ (25-500°C). IPS 99 is intended to be used for inlays, onlays, veneers and anterior/posterior PFM crowns.</p>	<p>Staining and/or characterization and glazing of ceramic materials from Ivoclar Vivadent and Wieland Dental:</p> <ul style="list-style-type: none"> - Veneering ceramics - Press ceramics - Milling ceramics - Zirconium oxide (framework and full-contour)
	<p>As a reference device, the Eris system includes shades, stains and glaze materials (currently sold under the brand name IPS Empress Universal) which are used for the characterization of all-ceramic restorations.</p> <p>In addition, Eris layering materials are porcelain powders used in the pressable ceramic system Empress 2, which is used for metal free single unit, and multiple unit bonded crown and bridge restorations.</p>	
Summary Indications	<p>IPS Ivocolor is a universal stains and glaze assortment. Its indication for individualized staining, characterization and glaze of ceramic materials is the same as IPS 99 shades, stains and glaze. IPS Ivocolor Essence are shade materials.</p> <p>The difference is that IPS Ivocolor can be used with both metal-ceramic and full-ceramic materials whereas the primary predicate - IPS 99 shades, stains and glaze - was supplied as part of the IPS 99 system for metal-ceramic and the reference device - Eris Layering Materials - shade, stains and glaze were supplied as part of the Eris system for full-ceramics</p>	

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<p>Working principle</p>	<p>IPS 99 shades and stains are used in very small amounts and thin layers to customize the esthetics of a restoration. The glaze is used for the glaze firing to achieve a shiny surface. Compatible with IPS 99, IPS InLine, IPS InLine PoM.</p> <p>The reference device - Eris Layering Materials - shades and stains are used in very small amounts and thin layers to customize the aesthetics of a restoration. The glaze is used for the glaze firing to achieve a shiny surface. Compatible with IPS Empress CAD, IPS Empress Esthetic</p>	<p>The Essence and Stains are used in very small amounts and thin layers to customize the aesthetic of a restoration. The Glaze is used for the glaze firing to achieve a shiny surface. Compatible with: IPS e.max Press IPS e.max CAD (crystalised) IPS e.max Ceram IPS e.max ZirPress IPS e.max ZirCAD (sintered) IPS Empress CAD IPS Empress Esthetic IPS Style IPS InLine IPS d.SIGN IPS Classic Zenostar (sintered)</p>
<p>Summary Working Principle</p>	<p>The working principle of the new product is the same as the primary predicate device and the reference device. The significant difference is that IPS Ivocolor will be marketed for use with the whole range of ceramic materials from Ivoclar Vivadent AG and the zirconium oxide ceramic material from Wieland Dental+Technik GmbH.</p> <p>This is a benefit to the dental technician because he can use a universal product.</p> <p>In the past each brand of ceramic was supplied in a system and had its own shades, stains and glaze.</p> <p>Technically it was not difficult to develop shade, stains and glaze which are compatible with a range of ceramics because the material is applied in very small quantities and very thin layers. The potential tension which can be developed between the shade, stains and glaze and the ceramic materials is minimal and does not cause a compatibility problem. It was only necessary to ensure that the CTE of the shade, stains and glaze is not above that of the ceramic material and this has been achieved.</p>	
<p>Summary Composition</p>	<p>The key ingredients, the silica-based dental glass ceramic are the same as the primary predicate device. IPS Ivocolor includes a new pigment. The biocompatibility of the new formulation was fully assessed and is equivalent to IPS 99</p>	

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Physical Properties	The product has been tested to ISO 6872 and meets the requirements.	The product has been tested to ISO 6872 and meets the requirements. IPS Ivocolor is the same Type and Class material as the primary predicate. The device has been tested for the following physical properties according to ISO 6872: <ul style="list-style-type: none">• Uniformity• Cleanliness• Radioactivity of ceramic• Color Coding• Flexural Strength• Coefficient of Linear Thermal Expansion• Glass Transition Temperature• Chemical Solubility
Summary Physical properties	The CTE and Glass transition temperature for IPS Ivocolor are slightly lower than those of the primary predicate. This is to ensure that the new materials are compatible with the chosen range of ceramics.	

Conclusion:

IPS Ivocolor is a ceramic material to stain, characterize and glaze ceramic restorations. It is compatible with several ceramic materials, both metal-ceramic and full-ceramic which is a benefit for the user. The indications, performance and biocompatibility match those of existing products, including the primary predicate IPS 99 and the reference device Eris Layering Materials.

Therefore IPS Ivocolor is substantially equivalent to the primary predicate device, IPS 99 One and IPS 99 Ceram (K121359).