



Food and Drug Administration
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May 20, 2016

Ivoclar Vivadent Ag
% Ms. Donna Hartnett
Director Regulatory Affairs
Ivoclar Vivadent, Inc.
175 Pineview Drive
Amherst, New York 14228

Re: K152103

Trade/Device Name: Ips Style Ceram, Ips Style Ceram One, Ips Style Press
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: April 8, 2016
Received: April 11, 2016

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" (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,

 Tina Kiang
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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)

Device Name

IPS Style Ceram, IPS Style Ceram One, and IPS Style Press

Indications for Use (Describe)

Intended Use: IPS Style Press

- Pressing on metal frameworks and superstructures for the fabrication of full-contour crowns and bridges (staining technique)
- Pressing on metal frameworks and superstructures for the fabrication of partially anatomic crowns and bridges (cut-back technique)
- Pressing of ceramic margins (metal-ceramic)
- Pressing of gingiva components (metal-ceramic)
- Processing on the most popular dental alloys in the CTE range of 13.8 – 14.5 10⁻⁶/K (25 – 500°C) (Cu < 1%, Ag ≤ 10%)
- Veneering with the layering materials of IPS Style in the conventional layering technique
- Characterization with IPS Ivocolor Shade and Essence stains
- Glazing with IPS Ivocolor Glaze

Intended Use: IPS Style Ceram and IPS Style Ceram One

- Conventional multi-layer veneering ceramic for the most popular dental alloys (including electroplating) in the CTE range of 13.8 – 15.2 x 10⁻⁶/K (25 – 500°C) (IPS Style Ceram)
- One-layer veneering ceramic for the most popular dental alloys (including electroplating) in the CTE range of 13.8 – 15.2 x 10⁻⁶/K (25 – 500°C) (IPS Style Ceram One)
- Veneers on refractory die material (only IPS Style Ceram)
- Characterization and veneering of IPS Style Press restorations
- Characterization with IPS Ivocolor Shade and Essence stains
- Glazing with IPS Ivocolor Glaze

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)

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510(K) SUMMARY

IPS Style Ceram-IPS Style Ceram One-IPS Style Press



Contact: Donna Marie Hartnett

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Date Prepared: May 16, 2016

Proprietary Name: **IPS Style Ceram**
IPS Style Ceram One
IPS Style Press

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

Predicate Device: IPS 99 One and IPS 99 Ceram (K121359)
IPS InLine PoM System (K071848)

Device Description:

IPS Style comprises both materials for the conventional veneering technique and the press technique.

- **IPS Style Ceram:** is available as Opaquer 870 in 42 Shades, Opaquer 960 in 42 shades, Margin Powder in 11 Shades, Dentin porcelain in 32 Shades, deep Dentin porcelain in 16 Shades, Incisal Porcelain in 10 Shades, Transparent Porcelain 7 Shades, Mamelon in 3 shades, Occlusal Dentin 2 Shades, Incisal Edge 1 Shade, Opal Effect in 6 Shades, Special Incisal 2 Shades, Inter Incisal 1 Shades, Cerv. Transparent 4 Shades, Add on Ceramic 4 Shades, Bleach Ceramic in 14 Shades, Gingiva Porcelain in 11 Shades and 4 Liquids.
- **IPS Style Ceram One:** is available in 16 Shades and Shades Guides
- **IPS Style Press:** Press Ingots LT is available in 8 Shades, Press Ingot HT in 8 Shades and Press Ingot Gingiva in 1 Shade.
- **IPS Style Liquids** including Build-up and Opaquer which burn out after firing.

510(K) SUMMARY

IPS Style Ceram-IPS Style Ceram One-IPS Style Press



Intended Use:

IPS Style Press

- Pressing on metal frameworks and superstructures for the fabrication of full-contour crowns and bridges (staining technique)
- Pressing on metal frameworks and superstructures for the fabrication of partially anatomic crowns and bridges (cut-back technique)
- Pressing of ceramic margins (metal-ceramic)
- Pressing of gingiva components (metal-ceramic)
- Processing on dental alloys in the CTE range of $13.8 - 14.5 \times 10^{-6}/K$ ($25 - 500^{\circ}C$) ($Cu < 1\%$, $Ag \leq 10\%$)
- Veneering with the layering materials of IPS Style in the conventional layering technique
- Characterization with IPS Ivocolor Shade and Essence stains
- Glazing with IPS Ivocolor Glaze

IPS Style Ceram and IPS Style Ceram One

- Conventional multi-layer veneering ceramic for dental alloys (including electroplating) in the CTE range of $13.8 - 15.2 \times 10^{-6}/K$ ($25 - 500^{\circ}C$) (IPS Style Ceram)
- One-layer veneering ceramic for dental alloys (including electroplating) in the CTE range of $13.8 - 15.2 \times 10^{-6}/K$ ($25 - 500^{\circ}C$) (IPS Style Ceram One)
- Veneers on refractory die material (only IPS Style Ceram)
- Characterization and veneering of IPS Style Press restorations
- Characterization with IPS Ivocolor Shade and Essence stains
- Glazing with IPS Ivocolor Glaze

Comparison to Predicate: The predicate devices to which IPS Style Ceram and IPS Style Ceram One has been compared are IPS 99 One and IPS 99 Ceram (K121359) and IPS Style Press has been compared to IPS InLine PoM System (K071848). IPS Style Ceram and IPS Style Ceram One are both ceramic systems for the fabrication of dental restorations on a dental alloy framework. For this application, IPS Style Ceram and IPS Style Ceram One have been compared to its predicate with regard to the chemical compositions, physical properties, operating principals and indications for use. The comparison shows that IPS Style Ceram and IPS Style Ceram One are substantially equivalent to the predicate device.

Biocompatibility: The device was evaluated in connection with ISO 10993-1:2009 Biocompatibility evaluation of medical device – Part 1 and tested for cytotoxicity and genotoxicity and the device possessed no cytotoxic potential and is considered to be non-mutagenic. The device was also evaluated for sensitization, irritation, acute and subchronic systemic toxicity, implantation and radioactivity. Based on these results, and a review of cytotoxicity and toxicological data of the predicate devices, the device is not expected to cause any adverse mucosal reactions and does not present a toxicological risk for the patient or user.

510(K) SUMMARY

IPS Style Ceram-IPS Style Ceram One-IPS Style Press



	Predicate devices K121359 & K071848	IPS Style
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 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 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>IPS Style Ceram and IPS Style Ceram One is a ceramic system for the fabrication of dental restorations on a dental alloy framework.</p> <ul style="list-style-type: none"> - Conventional multi-layer veneering ceramic for dental alloys (including electroplating) in the CTE range of $13.8 - 15.2 \times 10^{-6}/K$ (25 – 500°C) (IPS Style Ceram) - One-layer veneering ceramic for dental alloys (including electroplating) in the CTE range of $13.8 - 15.2 \times 10^{-6}/K$ (25 – 500°C) (IPS Style Ceram One) - Veneers on refractory die material (only IPS Style Ceram) - Characterization and veneering of IPS Style Press restorations - Characterization with IPS Ivocolor Shade and Essence stains - Glazing with IPS Ivocolor Glaze
	<p>IPS InLine PoM is a leucite ceramic system for pressing fully anatomical restorations on metal crown and bridge frameworks after the application of opaque, mainly in the posterior region. Alloy CTE range: $13.8-14.5 \times 10^{-6}/K$ (25-500°C).</p> <p>IPS InLine PoM should be used only with dental alloys having Ag<10%.</p>	<p>IPS Style Press;</p> <ul style="list-style-type: none"> - Pressing on metal frameworks and superstructures for the fabrication of full-contour crown and bridges (staining technique). - Pressing on metal frameworks and superstructures for the fabrication of partially anatomic crowns and bridges (cut-back technique). - Pressing of ceramic margins (metal-ceramic). - Pressing of gingiva components (metal-ceramic). - Processing on dental alloys in the CTE range of $13.8-14.5 \times 10^{-6}/K$ (25-500°C) Cu<1%, Ag<10%). - Veneering with the layering materials IPS Style in the conventional layering technique. - Characterization with IPS Ivocolor Shade and Essence stains. - Glazing with IPS Ivocolor Glaze.
Summary Indications	<p>The main difference between IPS Style and the IPS 99 range is that the IPS Style Ceram powders can be layered on IPS Style Press materials. In contrast, layering of IPS InLine Dentin, Incisal, Deep Dentin, Margin, Impulse and Gingiva materials on IPS InLine PoM was not included in the indication. The new materials have been specifically developed to be used together and the processing steps are compatible (e.g. firing temperatures).</p>	

510(K) SUMMARY

IPS Style Ceram-IPS Style Ceram One-IPS Style Press



	Predicate devices	IPS Style
Working principle	<p>IPS 99 is used as a conventional veneering material on dental alloy frameworks.</p> <p>IPS InLine PoM is used in the press-on technique on dental alloy frameworks.</p> <p>The products are available in a variety of shades and can be characterized using shades, stains and glaze in the same product family.</p>	<p>IPS Style includes materials for conventional veneering and pressing-on dental alloy frameworks.</p> <p>The products are available in a variety of shades.</p> <p>They are characterized using shades, stains and glaze in the IPS Ivocolor universal system</p>
Summary Working Principle	<p>IPS Style combines conventional veneering and press-on technology in one product family and one 510k application. The products have been developed together and in particular the IPS Style Ceram powders can be layered on IPS Style Press.</p> <p>In contrast to the predicates, IPS Style does not include shade, stain and glaze materials. It is intended that the new universal products IPS Ivocolor are used.</p>	
Summary Composition	<p>The key ingredients, is silica-based dental glass ceramic including the chemical elements: aluminum, lithium, zirconium, yttrium, potassium, phosphorous, magnesium, cerium, boron, calcium, sodium, titanium., strontium, fluoride, zinc, lanthanum.</p> <p>The device was evaluated in connection with ISO 10993-1:2009 Biocompatibility evaluation of medical device – Part 1 and tested for cytotoxicity and genotoxicity and the device possessed no cytotoxic potential and is considered to be non-mutagenic. Based on these results, and a review of cytotoxicity and toxicological data of the predicate devices, the device is not expected to cause any adverse mucosal reactions.</p> <p>The biocompatibility of the new formulation was fully assessed and is equivalent to IPS 99.</p> <p>There are some minor differences to the liquids compositions but this only affects handling as the liquids burn out during firing.</p>	
Physical Properties	<p>The product has been tested to ISO 6872 and meets the requirements. The product is also tested under ISO 9693 for Debonding/crack initiation strength and meets the requirements.</p>	<p>The product has been tested to ISO 6872 and meets the requirements. IPS Style Ceram, IPS Style Ceram One and IPS Style Press are the same Type and Class material as the predicate. The product is also tested under ISO 9693 for Debonding/crack initiation strength and meets the requirements.</p>
Summary Physical properties	<p>The specified flexural strength of IPS Style Press is lower than that of IPS InLine PoM. However the new value fulfils the requirements of the product-specific standard. The test results for flexural strength are significantly above the specification and similar to those of the predicate device IPS InLine PoM.</p> <p>In all other aspects the new products lie in the same ranges as the predicates. The variations are minimal. In addition the new products fulfill the requirements for metal-ceramic bond given in the product-specific standard.</p>	

Conclusion:

The main difference between IPS Style and the IPS 99 range is that the IPS Style Ceram powders can be layered on IPS Style Press materials. In contrast, layering of IPS InLine Dentin, Incisal, Deep Dentin, Margin, Impulse and Gingiva materials on IPS InLine PoM was not included in the indication. It combines conventional veneering and press-on technology in one product family.

510(K) SUMMARY

IPS Style Ceram-IPS Style Ceram One-IPS Style Press



Therefore IPS Style Ceram and IPS Style Ceram One and are substantially equivalent to the predicate device, IPS 99 One and IPS 99 Ceram. IPS Style Press is substantially equivalent to the predicate device, IPS InLine PoM System.