August 20, 2021

Ivoclar Vivadent AG
% Anderjeet Gulati
Sr. Manager QA & Regulatory Affairs
Ivoclar Vivadent Inc
175 Pineview Drive
Amherst, New York 14228

Re: K211916
Trade/Device Name: IPS e.max One
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain powder for clinical use
Regulatory Class: Class II
Product Code: EIH
Dated: June 9, 2021
Received: June 21, 2021

Dear Anderjeet Gulati:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael E. Adjodha, M.ChE.
Assistant Director
DHT1B: Division of Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210115

Device Name
IPS e.max® One

Indications for Use *(Describe)*
-Missing tooth structure in anterior and posterior teeth

Types of restorations:
- Veneers
- Inlays
- Onlays (e.g. occlusal veneers, partial crowns)
- Crowns

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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Contact: Anderjeet Gulati, Sr. Manager QA & Regulatory Affairs
Ivoclar Vivadent, Inc.
175 Pineview Drive
Amherst, New York 14228
716-264-2046
anderjeet.gulati@ivoclarvivadent.com

Company: Ivoclar Vivadent, AG
Bendererstrasse 2, Schaan, FL-9494, Liechtenstein
+423-235-3535

Date Prepared: August 19, 2021

Proprietary Name: **IPS e.max® One**

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

Predicate Device: IPS e.max CAD (K051705) by Ivoclar Vivadent, AG

Device Description: **IPS e.max® One** is a glass-ceramic block for the fabrication of fixed, full-contour single-tooth restorations in anterior and posterior teeth. IPS e.max One can be processed in milling machines and polished afterwards. A crystallization process is not necessary. The dentist starts with shade selection, preparation of the tooth based on guidelines for all-ceramic restorations, follow the recommended griding instruments and minimum layer thickness during finalizing and finishing, and finish with dental polishing.

Types of restorations:
-Veneers
-Inlays
-Onlays (e.g. occlusal veneers, partial crowns)
-Crowns

Indications for Use:

-Missing tooth structure in anterior and posterior teeth

Types of restorations:
- Veneers
- Inlays
- Onlays (e.g. occlusal veneers, partial crowns)
- Crowns

Comparison to Predicate: The primary predicate device to which IPS e.max One has been compared is Ivoclar Vivadent, AG IPS e.max CAD (K051705).

	Predicate Device:	Proposed Device:	Deviation	
Device	**Ivoclar Vivadent AG: IPS e.max CAD (K051705)**	**Ivoclar Vivadent AG: IPS e.max One (K211916)**	**Yes**	**No**
Indications for Use	**Indications for Use**: 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. 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.)	**Indications for Use**: -Missing tooth structure in anterior and posterior teeth Types of restorations: - Veneers - Inlays - Onlays (e.g. occlusal veneers, partial crowns) - Crowns	☒	☐
Precaution Measures/ Contraindications/ Processing restrictions/ Side effects	**Contraindications**: -Inlay-retained, cantilever, Maryland bridges -Pontic width anterior region > 11mm -Pontic width premolar region >9 mm -Temporary incorporation of IPS e.max CAD restorations -Fully veneered molar crowns -Very deep subgingival preparations -Patients with severely reduced residual dentition -Bruxism -Any other use not listed in the indications	**Contraindications:** - Patients with substantially reduced residual dentition **Limitations of use** – Bridge reconstructions – Anterior and posterior crowns with full (circular) veneer – Untreated bruxism (the use of an occlusal splint is indicated after incorporation) – Temporary insertion – Very deep sub-gingival preparations	☐	☒
Summary of Indications, Precaution Measures/ Contraindications/ Processing restrictions/ Side effects	The new device can be used for veneers, inlays, onlays and crowns (as explained under "working principle") like the predicate. In addition the predicate IPS e.max CAD from K051705 can be used for bridges as well – this indication is lacking for the new device. The contraindications for IPS e.max One and the predicate device IPS e.max CAD are basically the same, even though the wording slightly differs. The devices can be considered as substantially equivalent.			
Working Principle	IPS e.max CAD are lithium disilicate glass-ceramic blocks for the CAD/CAM technology. The blocks are processed in CAD/CAM units in their crystalline intermediate stage. After the IPS e.max CAD blocks are milled, the restoration is crystallized in a furnace.	IPS e.max One is a glass-ceramic block for the fabrication of fixed, full-contour single-tooth restorations in anterior and posterior teeth Types of restoration: -Veneers -Inlays -Onlays (e.g. occlusal veneers, partial crowns) -Crowns IPS e.max One are processed in milling machines and polished afterwards. A crystallization process is not necessary.	☒	☐

Summary of Working Principle	Both devices are glass-ceramic blocks for the CAD/CAM technology. The main difference is that the new blocks (IPS e.max One) don`t need to be crystallized after the milling process. This is an advantage for the customer because the process is less time consuming without the crystallization step. Therefore, the working principle is basically the same for both devices and they are substantially equivalent.			
Delivery forms/dosage	Ceramic blocks in different shades, translucencies and sizes: - HT I12, C14, BL1, BL2, BL3, BL4, A1, A2, A3, A3.5, A4, B1, B2, B3, B4, C1, C2, C3, D2, D3, D4 - LT I12, C14, C16, B32 BL1, BL2, BL3, BL4, A1, A2, A3, A3.5, A4, B1, B2, B3, B4, C1, C2, C3, D2, D3, D4 - MO C14 Shades 0, 1, 2, 3, 4, - MT C14 Shades BL2, BL3, BL4, A1, A2, A3 B1 - Impulse C14 Shades Opal 1, Opal 2	Ceramic blocks in different shades, translucencies and sizes: - Multi C14, A1, A2, A3, A3.5, B1, B2, C2, D2, BL1, BL3 - HT C14, A1, A2, A3, A3.5, B1, B2, C2, D2, BL1, BL3	☒	☐
Summary of Delivery forms/dosage	The new device is available in less shades and translucencies compared to the predicate device. The new device is available with a color gradient ("Multi") which is a new feature compared to the predicate.			
Storage Conditions	No shelf life	No shelf life	☐	☒
Summary of Storage Conditions	No difference.			
Principles of Operation	**Step-by-step:** - Shade selection - Preparation - Finishing - Completion with Crystallization	**Step-by-step:** - Shade selection - Preparation - Finishing - Completion	☒	☐
Summary Principles of operation	Basically, the principle of operation is substantially equivalent between the predicate and the new device. The slight difference in the step-by-step application is explained through the fact, that there is no crystallization step needed for the new device IPS e.max One which results in time saving for the customer.			
Summary of Chemical Composition	Both products are dental glass-ceramic blocks used for the CAD/CAM technology in order to create dental restorations. The new formulation for IPS e.max One has been thoroughly assessed for biocompatibility and the biocompatibiility is substantially equivalent to the predicate device. See biocompatibility assessment for IPS e.max One is part of the submission.			
Finished Device Specification	*ISO 6872:1995 – Dental Ceramic*	*ISO 6872:2015 – Dentistry – Ceramic materials*	☒	☐
Summary of Finished Device Specification	The predicate device was compliant with ISO 6872 from 1995. IPS e.max One is following the same standard from 2015. IPS e.max Ones is a class 3, Type II according to ISO 6872:2015.			
Sterilization	Not applicable. No sterilization recommendation.	Not applicable. No sterilization recommendation.	☐	☒
Single use	Consumable material	Consumable material	☐	☒
Summary of Performance Specification	The predicate device IPS e.max CAD followed the requirements from ISO standard 6872: Dental Ceramic from 1995. The new device IPS e.max One follows the requirements of the same standard, however form year 2015.			

	Therefore, the performance criteria can be considered as substantially equivalent.

Substantial Equivalence to the predicate:

IPS e.max CAD and IPS e.max One are both millable blocks used for dental restorations. The products are both dental ceramic materials even though the chemical composition differs. The new device covers the indications offered by the predicate device but lacks the indications of bridges. Both blocks are milled in CAD/CAM milling machines. The predicate device needs to undergo a crystallization process after milling which is not needed for IPS e.max One.

Therefore, IPS e.max One is substantially equivalent to the predicate device IPS e.max CAD.

Differences:

The new device can be used for veneers, inlays, onlays and crowns (as explained under "working principle") like the predicate. In addition, the predicate IPS e.max CAD from K051705 can be used for bridges as well – this indication is lacking for the new device.

The working principle of the predicate and the new device is basically the same. Both devices are blocks milled in CAD/CAM milling machines, but the crystallization process is not needed for the new device IPS e.max One compared to the predicate.

The chemical composition is different. However, both devices are dental ceramic materials.

Non-clinical performance testing:

Bench testing was performed to test the physical properties included in the Finished Device Specification for the subject device including: flexural strength, linear thermal expansion (CTE), chemical solubility, glass transition temperature, and radioactivity according to EN ISO 6872:2015- Dentistry – Ceramic materials (ISO 6872:2015).

Biocompatibility:

The subject device was also evaluated for Biocompatibility according to ISO 10993-1:2009, ISO 7405:2018 and ISO 14971:2019. The biological evaluation was performed based on toxicological data on relevant component materials / compounds, information on prior use of relevant component materials / compounds, data from biological tests, data on the history of clinical use or human exposure. On the basis of the information included in the biological evaluation report it can be concluded that the extract of the product is not cytotoxic, no sensitizing potential is reported for lithium disilicate glass-ceramic blocks (LS_2) as New Millable GC does not induce oral mucosal irritation. New Millable GC holds no potential for material-mediated pyrogenicity, New Millable presents no risks for acute, sub-acute, sub-chronic or chronic toxicity. Extracts of the product are not genotoxic, the risk of carcinogenicity induced by the product is negligible, the products have no direct contact to pulp or dentin. It can be concluded that the product does not represent a toxicological risk for the patient and the user.

On the basis of the toxicological evaluation of the product and the longstanding worldwide clinical use of similar materials it can be concluded that the benefits provided by the final product will

exceed any potential risks produced by device materials providing that instructions for use have been followed.

Conclusion:

IPS e.max CAD and IPS e.max One are both millable blocks used for dental restorations. The products are both dental ceramic materials even though the chemical composition differs. The new device covers the indications offered by the predicate device but lacks the indications of bridges. Both blocks are milled in CAD/CAM milling machines. The predicate device needs to undergo a crystallization process after milling which is not needed for IPS e.max One.

Therefore, IPS e.max One is substantially equivalent to the predicate device IPS e.max CAD.