March 10, 2026

Ivoclar Vivadent, Inc.
Anderjeet Gulati
Sr. Manager of QA & Regulatory Affairs
175 Pineview Dr.
Amherst, New York 14228

Re: K253953
Trade/Device Name: IPS e.max Zirconia
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: December 2, 2025
Received: December 10, 2025

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the Medical Device File (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

For Michael E. Adjodha, M.ChE., RAC, CQIA
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K253953

Device Name
IPS e.max Zirconia

Indications for Use *(Describe)*
– Missing tooth structure in anterior and posterior teeth
– Partial edentulism in the anterior and posterior region

Types of restorations
- Crowns
- 3-unit bridges
- Multi-unit bridges with 2 connected pontics
- Multi-unit bridges with up to 4 connected anterior pontics
- Cantilever bridges with one pontic
- Adhesive bridges
- Hybrid bridges
- Hybrid structures and hybrid crowns
- Inlays
- Onlays
- Veneers

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.

510(K) SUMMARY
K253953

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Date Prepared: March 10, 2026

Proprietary Name: **IPS e.max® Zirconia**

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

Common Name: Porcelain powder for clinical use.

Predicate Device: Zenostar MO, Zenostar T, Zenostar VisualizerZr (K142233) by Wieland Dental (a member of the Ivoclar Vivadent Group)

Reference Device: Cerono yo ML (K241557) Dentsply Sirona

Device Description:

IPS e.max® Zirconia is a yttrium-stabilized zirconium oxide for the fabrication of fixed all-ceramic restorations according to ISO 6872:2024 Type 2, Class 5. Dental restorations are milled out of the zirconia discs through the CAD/CAM process. The zirconia restorations can be stained and characterized, before or after the final sintering process. The IPS e.max Zirconia Color Liquids/IPS e.max Zirconia Effect Liquids are ready-to-use solutions that burn out without leaving residue for the visible staining and characterization of unsintered zirconium oxide restorations.

IPS e.max Zirconia is available in Discs with a diameter of 98.5 mm width and various thickness and shades and Liquids: dipping and brushing liquids, diluter, effect liquid, opaque

Principles of operation:

Application
-Designing, nesting and fabricating restorations in the CAD/CAM process
-Finishing restorations in unsintered state
-Optional infiltrating
-Sintering the restoration

Indications for Use:

– Missing tooth structure in anterior and posterior teeth
– Partial edentulism in the anterior and posterior region

Types of restorations

-Crowns
-3-unit bridges
-Multi-unit bridges with 2 connected pontics
-Multi-unit bridges with up to 4 connected anterior pontics
- Cantilever bridges with one pontic
- Adhesive bridges
- Hybrid bridges
- Hybrid structures and hybrid crowns
- Inlays
- Onlays
- Veneers

Comparison to Predicate:

The primary predicate device to which IPS e.max Zirconia has been compared is Zenostar MO, Zenostar T, Zenostar Visualizr (K142233) Wieland Dental (a member of the Ivoclar Vivadent Group)

Comparison Matrix:

	Primary Predicate Device:	**Proposed Device:**	**Deviation**	
Device	**Wieland Dental: Zenostar MO, Zenostar T, Zenostar Visualizer (K142233)**	**Ivoclar Vivadent AG: IPS e.max Zirconia**	**Yes**	**No**
Indications for Use	**Indications for Use** Zenostar MO and Zenostar T consist of machinable zirconia discs for the preparation of full ceramic crowns, onlays and bridges (anterior and molar). Zenostar VisualiZr is for the temporary dyeing of Zenostar Color Zr solutions according to the Instructions for Use.	**Indications for Use:** - Missing tooth structure in anterior and posterior teeth - Partial edentulism in the anterior and posterior region *Types of restorations* - Crowns - 3-unit bridges - Multi-unit bridges with 2 connected pontics - Multi-unit bridges with up to 4 connected anterior pontics - Cantilever bridges with one pontic - Adhesive bridges - Hybrid bridges - Hybrid structures and hybrid crowns - Inlays - Onlays - Veneers	☒	☐

Precaution Measures/ Contraindications / Processing restrictions/ Side effects	**Contraindications Zenostar T, MO:** - More than two adjacent pontics - Very deep subginigival preparations - Patients with inadequate natural dentition - Bruxism for veneered structures - Two or more adjacent cantilever units - All other applications which are not included in the indications - Insertion as a provisional restoration **Contraindications Zenostar VisualiZr:** Once it has been mixed with Zenostar Color Zr, Zenostar VisualiZr is not colour stable over time. Therefore, VisualiZr colour concentrates should not be added to the Zenostar Color Zr solutions until immediately before they are applied. Do not use Zenostar VisualiZr undiluted.	**Contraindications** The use of the product is contraindicated if the patient is known to be allergic to any of its ingredients. **Limitations of use** The use of the product is not permitted in the following cases: – Untreated bruxism – Reuse of the final restoration – Temporary insertion – One-piece abutments – Use of the product for indications/types of restorations not intended by the manufacturer **Side effects** None known to date. **Interactions** None known to date.	☒	☐
Summary of Indications, Precaution Measures/ Contraindications / Processing restrictions/ Side effects	The predicate device and the new device IPS e.max Zirconia are both zirconia discs which can be used for the fabrication of dental crowns, bridges and onlays. The indication of inlays and veneers is new for the new device compared to the predicate, however this is a common indication for this type of product. Some parts of the contraindications can be found in the section “Limitations of use” in the instructions of the new device IPS e.max Zirconia. No contraindications are mentioned for the liquids of IPS e.max Zirconia, as these are ready-to-use solutions. Therefore, the indications for use and contraindications can be considered as substantially equivalent.			
Working Principle	Zenostar MO and Zenostar T are pre-sintered Zirconia discs with 98.5mm width and various thickness for use in the fabrication of dental prosthesis through the CAD/CAM milling technology. After milling, they are to be sintered at a high temperature to its full density, in order to achieve its expected physical properties. Prior to sintering, restorations made from Zenostar T or Zenostar MO can be individually shaded by infiltrating them with Zenostar Color Zr liquids.	IPS e.max Zirconia is an yttrium-stabilized zirconium oxide for the fabrication of fixed all-ceramic restorations according to ISO 6872:2024 Type 2, Class 5. The zirconia discs with 98.5mm width consist of the following zones: incisal zone, transition zone and dentin zone. Out of the zirconia discs restorations in the CAD/CAM process are milled. The unsintered zirconia restorations can be stained and characterized using IPS e.max Zirconia Color liquids or IPS e.maxZirconia Effect liquids, which are ready-to-use solutions that burn out without leaving residue. The last step is the sintering process of the final restoration.	☐	☒
Summary of Working Principle	The working principle for the new product IPS e.max Zirconia is substantially equivalent to the predicate: both devices are zirconia discs for the fabrication of dental restorations.			
Delivery forms/dosage	Discs with a diameter of 98.5 mm width and various thickness and shades Liquids: red, blue and yellow colour concentrates for dyeing Zenostar Color Zr solutions.	Discs with a diameter of 98.5 mm width and various thickness and shades Liquids: dipping and brushing liquids, diluter, effect liquid, opaque	☐	☒
Summary of Delivery forms/dosage	The delivery forms are zirconia discs in various shades and thicknesses. Delivery forms are considered to be substantially equivalent.			
Storage Conditions	No special storage conditions for discs Liquids: 2 – 28°C	**IPS e.max Zirconia discs :** - Store the product in its original packaging. - Protect the product from impacts or unbuffered vibrations.	☒	☐

		- Store the product in a dry place. **IPS e.max Zirconia Color Liquid:** - Storage temperature: 2–28 °C - Date of expiration: See note on packaging		
Summary of Storage Conditions	To protect the discs of IPS e.max Zirconia from damage and chipping, the storage conditions have been adapted for the new device. Beside the above mentioned information, no further storage conditions, like temperature are required for the discs of the predicate and the new device. The liquids have the same storage temperature. Therefore, storage conditions are considered as substantially equivalent.			
Directions for use (step-by-step)	**Basic steps:** - Milling of discs - Sintering - Finishing of the restoration	**Basic steps:** - Milling of discs - Sintering - Finishing of the restoration	☐	☒
Summary Principles of operation	The basic steps are basically the same and can be considered as substantially equivalent.			
Summary of Chemical Composition	The main ingredients Zirconium oxide, Yttrium oxide, Hafnium oxide and Aluminium oxide are used for the predicate as well as for the new device IPS e.max Zirconia even though in different quantities. Coloring and sintering agents in form of oxides are used to provide the shading of the discs. The biocompatibility has been thoroughly assessed for the new device IPS e.max Zirconia.			
Finished Device Specification	*EN ISO 6872:2008 – Dentistry – Ceramic materials* *Zenostar MO and Zenostar T are classified as Type II* *Class 6*	*EN ISO 6872:2024 – Dentistry – Ceramic materials* *IPS e.max Zirconia is classified as Type II Class 5*	☐	☒
Summary of Finished Device Specification	The predicate and new devices follow the same standard: ISO 6872.			
Sterilization	The products are not sold sterile nor sterilized by the user.	The products are not sold sterile nor sterilized by the user.	☐	☒
Single use	Consumable material	Consumable material	☐	☒

Substantial Equivalence to the predicate:

The new device can be used with additional indications (inlays and veneers) compared to the predicate device. However, these are common indications for use for this type of devices.
The contraindications have been slightly adapted for the new device.
Even though, indications and contraindications can be considered as substantially equivalent.

The biocompatibility of the new formulation was fully assessed and is considered substantially equivalent. The device performance was tested according to ISO 6872 and was found to meet the relevant performance criteria.

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

Differences:

Indication differs in that IPS e.max Zirconia can be used with additional indications (inalys and veneers). This is a common indication for this type of product. Some parts of the contraindications can be found in the section “Limitations of use” in the instructions of the new device IPS e.max Zirconia. No contraindications are mentioned for the liquids of IPS e.max Zirconia, as these are ready-to-use solutions.

The Design Parameters vary between the new device and the predicate. More conservative design parameters have been released for the new device IPS e.max Zirconia. The reason are the different zones of the discs: incisal, transition and dentin zone with different strengths. The different zones enable the fabrication of highly esthetic restorations compared to single shaded discs of the predicate device.

Storage Conditions differ in that to protect the discs of IPS e.max Zirconia from damage and chipping, the storage conditions have been adapted for the new device.

The Chemical Composition in IPS e.max Zirconia is slightly different in the quantities, but the main ingredients are used for the predicate as well as for the new device. The biocompatibility of the new formulation was assessed and is considered substantially equivalent.

The Device Specification for chemical solubility (10 µg * cm^{-2} vs 100 µg * cm^{-2}) can explained with the different versions of ISO 6872. The linear thermal expansion (CTE) is slightly lower compared to the predicate. However, it conforms to the requirements of ISO 6872:2024.

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 6872:2024 Dentistry – Ceramic Materials

Biocompatibility:
The subject devices were evaluated for Biocompatibility according to ISO 10993, ISO 7405, ISO 21726:2019 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. Based on the information included in the biological evaluation reports it can be concluded that the products under evaluation are acceptable in relation to its clinical benefit.

- Extracts of the products under assessment are not cytotoxic
- The products under assessment hold a negligible sensitizing potential
- The products under assessment are not irritant

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 the instructions for use have been followed.
The toxicological risks of the subject device are substantially equivalent to those of the predicate device.

Conclusion:
The predicate devices and the new device IPS e.max Zirconia are both pre-sintered zirconia discs to manufacture fixed all-ceramic dental restorations. While using a CAD/CAM process final restorations like crowns, bridges etc. are milled. Sintering of the restorations brings them into their final state. Before sintering optional characterization with coloring liquids can be performed.

Therefore, the new device **IPS e.max Zirconia** can be considered as substantially equivalent to the predicate device.