



April 6, 2026

Aidite (Qinhuangdao) Technology Co., Ltd.  
% Boyle Wang  
General Manager  
Shanghai Truthful Information Technology Co., Ltd.  
Room 1801, No. 161 East Lu Jiazui Rd., Pudong  
Shanghai, 200120  
CHINA

Re: K253036

Trade/Device Name: Light-curing Coloring Materials (ALCM)  
Regulation Number: 21 CFR 872.3690  
Regulation Name: Tooth Shade Resin Material  
Regulatory Class: Class II  
Product Code: EBF  
Dated: September 22, 2025  
Received: September 22, 2025

Dear Boyle Wang:

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), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

**MICHAEL E. ADJODHA -S**

Michael E. Adjodha, MChE, 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

## Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K253036

?

Please provide the device trade name(s).

?

Light-curing Coloring Materials (ALCM)

Please provide your Indications for Use below.

?

This product is used for the individualized staining of directly placed and laboratory-fabricated acrylic resin restorations, composite resin restorations, and resin-based ceramics

Please select the types of uses (select one or both, as applicable).

- Prescription Use (Part 21 CFR 801 Subpart D)  
 Over-The-Counter Use (21 CFR 801 Subpart C)

?

## 510(k) Summary

**K253036**

This summary is submitted in accordance with 21 CFR 807.92.

### **1.0 Submission Sponsor**

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### **Designated Submission Correspondent**

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Date of Preparation: April.2,2026

### **2.0 Device Information**

Trade name: Light-curing Coloring Materials  
Common name: Light-curing Coloring Materials  
Model: ALCM  
Classification name: Material, Tooth Shade, Resin  
Production code: EBF  
Regulation number: 21 CFR 872.3690  
Classification: Class II  
Panel: Dental

### **3.0 Identification of Predicate Device**

510(k) Number: K121230  
Trade/Product Name: IPS Empress®D Direct Color and IPS Empress®) Direct  
Opaque  
Manufacturer: IVOCLAR VIVADENT AG

#### **4.0 Device Description**

The subject device, Light-curing Coloring Materials (Model: ALCM), is a dental restorative accessory material intended for individualized staining of directly placed and laboratory-fabricated acrylic resin restorations, composite resin restorations, and resin-based ceramics.

The device is supplied in a non-sterile condition and packaged in food-grade PE bottles. It is available in fill volumes of 1 ml, 2.5 ml, 5 ml, and 10 ml. The formulation and manufacturing process are identical across all specifications; only the filling quantity differs.

The device is offered in a variety of shades, including Transparent, Brown, Blue, Color A Series, Color B Series, White, Off White, Dark Red, Light Red, Gray, Yellow, Pink Orange, Orange, and Purple Red.

#### **5.0 Indication for Use Statement**

This product is used for the individualized staining of directly placed and laboratory-fabricated acrylic resin restorations, composite resin restorations, and resin-based ceramics

#### **6.0 Non-clinical Test Conclusion**

Bench Testing:

Physical and mechanical properties of the subject device were evaluated in accordance with FDA-recognized standards ISO 4049 Dentistry – Polymer-based restorative materials and ISO 20795-1:2013 Dentistry - Base polymers - Part 1: Denture base polymers.

- Performance testing including Appearance, Sensitivity to light, Water Sorption, Water Solubility, Shade consistency and Color stability, Flexural strength and Film Thickness were conducted in accordance with ISO 4049.

- Residual monomer testing were conducted in accordance with ISO 20795-1:2013.

The test results demonstrated the Subject device meets the property requirements of the referenced standards.

Biocompatibility Testing:

The nature of body contact of materials used in the design of the Light-curing Coloring Materials were classified as being “External Communicating device with tissue/bone/dentin” with contact duration of >30 days. The biocompatibility testing was performed according to FDA currently-recognized versions of biocompatibility consensus standards ISO 10993-1:2018 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process and ISO 7405:2018 Dentistry – Evaluation of biocompatibility of medical devices used in dentistry.

The following biological safety aspects have been addressed:

- Cytotoxicity – ISO 10993-5
- Sensitization – ISO 10993-10
- Irritation – ISO 10993-23
- Acute Systemic Toxicity- ISO 10993-11
- Pyrogen Test- ISO 10993-11
- Mouse Lymphoma TK Assay- ISO 10993-3
- Bacterial Reverse Mutation Test- ISO 10993-3
- Subchronic Systemic Toxicity- ISO 10993-11

Sterility and Shelf-Life Testing:

The device is provided non-sterile.

From the Shelf life testing, Light-curing Coloring Materials has a shelf life of 2 years.

## **7.0 Technological Characteristics and Substantial Equivalence**

The following table shows similarities and differences of use, design, and material between our device and the predicate devices.

**Table 1- Comparison of Technology Characteristics**

<b>Item</b>	<b>Subject Device</b>	<b>Predicate Device</b>	<b>Remark</b>
510(k) No.	K253036	K121230	
Product Name	Light-curing Coloring Materials	IPS Empress®D Direct Color and IPS Empress®) Direct Opaque	--
Product Code	EBF	EBF	Same
Regulation No.	21 CFR 872.3690	21 CFR 872.3690	Same
Class	II	II	Same
Intended Use/ Indication for Use	This product is used for the individualized staining of directly placed and laboratory-fabricated acrylic resin restorations, composite resin restorations, and resin-based ceramics	IPS Empress Direct Color: Individualized characterization of direct and lab-fabricated composite resin restorations; masking of discolored tooth structure; characterization of chairside CAD/CAM veneers. IPS Empress Direct Opaque: Masking exposed metal surfaces when repairing defective ceramic and composite veneers intraorally; Masking of discolored tooth structure.	Same (Analysis 1)
Prescription Use	Yes	Yes	Same
Technology	Light-curing resin liquid for dental restorative surface staining (applied	Light-curing resin liquid for esthetic characterization	Same

	chairside or in laboratory)	(surface staining/glazing) of direct and indirect composite resin restorations and CAD/CAM veneers	
Materials	--The transparent color of this product consists solely of acrylic resin and photoinitiator. --Other colors consist of acrylic resin, silicon dioxide (silica), pigment, and photoinitiator.	--Brown shade: Bis-GMA, D3MA, UDMA, silicone oxide, TEGDMA, camphorquinone, aminobenzoate; --Remaining shades: Bis-GMA, UDMA, TEGDMA, silicone oxide	Similar
Materials Shades	Transparent, Brown, Blue, Color A Series, Color B Series, White, Off White, Dark Red, Light Red, Gray, Yellow, Pink Orange, Orange, Purple Red.	White, Honey Ochre, Blue Grey, Brown	Different (Analysis 2)
Shelf-Life	2 years	2 years	Same
Polymerization (Curing) Method	Light-activated free-radical polymerization of acrylic-resin based coloring material. Curing requires UV/visible light 385–405 nm. Solidification occurs via photoinitiator activation, forming both chemical bonds and mechanical retention with the substrate.	IPS Empress Direct Color cures with light in the wavelength range of 400–500 nm.	Similar
Polymerization Equipment	Chairside curing light ( $\geq 650$ mW/cm <sup>2</sup> , 3.5 min, $\leq 4$ mm distance, 385–405 nm); Laboratory curing oven ( $\geq 400$ mW/cm <sup>2</sup> , 5 min, 385–405 nm).	Chairside curing light, 400–500 nm wavelength; 500–900 mW/cm <sup>2</sup> for 20 s or 1000–1300 mW/cm <sup>2</sup> for 10s	Different (Analysis 3)
Performance Testing	ISO 4049:2019	ISO 4049:2019	Same
Appearance	The product is a homogeneous liquid without visible impurities or foreign matter.	Homogeneous light-curing resin liquid, shade-specific, free of visible impurities	Same
Water Sorption	23.94 ug/mm <sup>3</sup>	24.69 ug/mm <sup>3</sup>	Different (4)
Water Solubility	0.57 ug/mm <sup>3</sup>	1.69 ug/mm <sup>3</sup>	
Flexural Strength	187.738 MPa	185.586 MPa	
Shear bond strength	22.94MPa	17.73MPa	
Dyeability	Purple: 17.09 Transparent color: 0.69 Brown: 10.08	Brown: 8.45 Grey: 4.74	
Staining resistance	Purple: Red wine- $\Delta E = 2.58$ ; Coffee- $\Delta E = 3.16$ ; Coke- $\Delta E =$	Brown: Red wine- $\Delta E = 1.31$ ; Coffee- $\Delta E = 0.74$ ; Coke- $\Delta E =$	

	2.67 Brown: Red wine- $\Delta E = 2.61$ ; Coffee- $\Delta E = 3.84$ ; Coke- $\Delta E = 3.07$ Grey: Red wine- $\Delta E = 2.44$ ; Coffee- $\Delta E = 2.28$ ; Coke- $\Delta E = 2.52$	1.63 Grey: Red wine- $\Delta E = 7.23$ ; Coffee- $\Delta E = 5.04$ ; Coke- $\Delta E = 1.86$	
Particle size	152.01nm	191.235nm	
Film Thickness	Transparent: 7.0 $\mu$ m; Purple Red: 7.2 $\mu$ m; Brown: 7.4 $\mu$ m	Brown: 7.4 $\mu$ m Gray: 7.6 $\mu$ m	
Residual Monomer	Meet the requirement of ISO 20795-1:2013, residual monomer (MMA) $\leq 2.2\%$ . Transparent: 0.030% Brown: 0.027% Purplish Red: 0.028%	Not publicly Available	Different (5)
Sterile	Non-sterile	Non-sterile	Same
Biocompatibility	Comply with ISO 10993-1:2018, and ISO 7405:2018	Comply with ISO 10993-1, ISO 7405:2018	Same

**Analysis\*:**

1) The "Indication for Use" of Light-curing Coloring Materials and IPS Empress®D Direct Color are considered substantially equivalent. Both the subject and predicate devices are intended to provide individualized esthetic characterization of dental restorative materials. The subject device is intended for individualized staining/characterization of resin-based restorations and ceramics, which falls within the same overall purpose as the predicate device. Therefore, the intended use of the subject device is substantially equivalent to that of the predicate device.

2) The subject device offers a broader range of material shades compared to the predicate device; however, this difference only reflects an expansion of available color options for esthetic customization. It does not alter the fundamental formulation, mechanism of action, or intended clinical use. Both devices serve the same purpose of esthetic characterization of dental restorations. Therefore, the difference in shade availability does not raise new safety or effectiveness concerns and the subject device is substantially equivalent to the predicate device.

3) The subject device specifies curing using light sources in the 385–405 nm range with defined intensity and time conditions, while the predicate device specifies curing in the 400–500 nm range with alternative intensity–time combinations. These differences represent variations in the curing parameters and acceptable equipment, but both devices rely on the same fundamental mechanism of light-activated polymerization via photoinitiator activation. The differences do not introduce a new

mechanism of action or clinical use, and both devices achieve comparable curing of resin-based restorative materials. Since both devices are designed for the same intended use, have similar technological principles, and meet the performance standards of ISO 4049:2019, the differences do not affect their substantial equivalence.

4) Both the subject device and the predicate device (IPS Empress® Direct Color, K121230) were evaluated according to the requirements of ISO 4049:2019 Dentistry—Polymer-based restorative materials. Comparative testing was conducted on key performance attributes including appearance, sensitivity to ambient light, water absorption, solubility, color stability, shear bond strength, dyeability, color masking, flexural strength, staining resistance, particle size and film thickness. The results demonstrated that the subject device met all applicable ISO 4049:2019 criteria and showed no significant differences compared to the predicate device. Therefore, the performance characteristics of the subject device are considered substantially equivalent to those of the predicate device.

5) Residual monomer testing for the subject device was conducted in accordance with ISO 20795-1:2013, demonstrating residual monomer (MMA) levels  $\leq 2.2\%$ , with measured values (0.027%–0.030%) well below the acceptance limit. Although residual monomer data for the predicate device are not publicly available, both devices are composed of similar polymer-based materials and are subject to the same recognized standards and regulatory expectations. Biocompatibility for both devices complies with ISO 10993-1 and ISO 7405, indicating comparable biological safety profiles. Therefore, these differences do not affect the conclusion of substantial equivalence.

## **8.0 Summary of Clinical Test**

Clinical testing was not required for this submission.

## **9.0 Conclusion**

The conclusions drawn from the comparison and analysis above demonstrate that the subject device is substantially equivalent to the legally marketed predicated device.