March 5, 2026

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

Re: K252450
Trade/Device Name: Adhese 2
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: Class II
Product Code: KLE
Dated: July 24, 2025
Received: August 4, 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 13484 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 device master record (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,

MICHAEL E. ADJODHA -S

Michael E. Adjodha, MChE, RAC, CQIA
Assistant Director
DHT1B: Division of Dental and
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OHT1: Office of Ophthalmic, Anesthesia,
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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)*
K252450

Device Name
Adhese 2

Indications for Use *(Describe)*
– Missing tooth structure
– Defective restorations

Areas of application:
a. Pure self-curing of Adhese 2 only in combination with VivaPen DC cannulas and DC applicators
– Adhesive cementation of indirect restorations and endodontic posts using Variolink® Esthetic DC in combination with all etching techniques.
– Adhesive cementation of indirect restorations and endodontic posts using light- and dual-curing luting composites in combination with the etch & rinse technique.
b. Light-curing of Adhese 2 at 500 to 1400 mW/cm2 (10 seconds) or at 1800 to 2200 mW/cm2 (5 seconds)
– Adhesive cementation of indirect restorations with light- and dualcuring luting composites
– Directly placed reconstructive build-ups and core build-ups made with light-, self- and dual-curing composites
– Directly placed light-curing composite and compomer restorations
– Repair of fractured composite and compomer restorations
– Desensitization of hypersensitive cervical areas
(Note: Provide additional cooling with an air syringe when applying the product.)
– Sealing of prepared tooth surfaces before temporary/permanent cementation of indirect restorations
c. Light-curing of Adhese 2 using Bluephase PowerCure in the 3sCure curing mode
– Only restorations in the posterior region of permanent dentition

(Class I and II, including the replacement of individual cusps) when light-cured from the occlusal aspect.

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

K252450

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Date Prepared: August 1, 2025

Proprietary Name: **Adhese® 2**

Classification Name: Agent, Tooth Bonding, Resin (872.3200)
(Classification Code KLE)

Common Name: Resin tooth bonding agent

Predicate Device: Adhese Universal DC (K210804) by Ivoclar Vivadent AG, Liechtenstein

Device Description:

Adhese® 2 is a dual-curing single-component dental adhesive for enamel and dentin that is compatible with all etching techniques (self-etch, selective-enamel-etch and etch & rinse techniques).
The areas of application include adhesive cementation of indirect restorations and direct restorative procedures.
Adhese 2 can either be light-cured for 10 s at a light intensity of 500 to 1,400 mW/cm2 or for 5 s at a light intensity of 1,800 to 2,200 mW/cm2.
In the restoration of Class I and II cavities, Adhese 2 can be light-cured in only 3 s from the occlusal aspect at a light intensity of 2,700 to 3,300 mW/cm2.

Adhese 2 is available in the VivaPen®, in bottles or in Free Stand® Single Dose units.

Principles of operation:

1. Isolation
2. Pulp protection/cavity liner
3. Conditioning with phosphoric acid gel
4. Handling of the VivaPen, bottle and Free Stand Single Dose unit
5. Application of the adhesive
6. Application of the restorative or luting composite

Indications for Use:

– Missing tooth structure

– Defective restorations

Areas of application:

a. Pure self-curing of Adhese 2 only in combination with VivaPen DC cannulas and DC applicators

– Adhesive cementation of indirect restorations and endodontic posts using Variolink® Esthetic DC in combination with all etching techniques.

– Adhesive cementation of indirect restorations and endodontic posts using light- and dual-curing luting composites in combination with the etch & rinse technique.

b. Light-curing of Adhese 2 at 500 to 1400 mW/cm2 (10 seconds) or at 1800 to 2200 mW/cm2 (5 seconds)

– Adhesive cementation of indirect restorations with light- and dual-curing luting composites

– Directly placed reconstructive build-ups and core build-ups made with light-, self- and dual-curing composites

– Directly placed light-curing composite and compomer restorations

– Repair of fractured composite and compomer restorations

– Desensitization of hypersensitive cervical areas

(Note: Provide additional cooling with an air syringe when applying the product.)

– Sealing of prepared tooth surfaces before temporary/permanent cementation of indirect restorations

c. Light-curing of Adhese 2 using Bluephase

PowerCure in the 3sCure curing mode

– Only restorations in the posterior region of permanent dentition

(Class I and II, including the replacement of individual cusps) when light-cured from the occlusal aspect.

Comparison to Predicate:

The primary predicate device to which Adhese 2 has been compared is Ivoclar Vivadent AG's Adhese Universal DC (K210804).

Comparison Matrix :

	Predicate Device:	Proposed Device:	Deviation	
Device	**Ivoclar Vivadent AG: Adhese Universal DC (K210804)**	**Ivoclar Vivadent AG: Adhese 2**	**Yes**	**No**
Indications for Use	– Missing tooth structure – Defective restorations	– Missing tooth structure – Defective restorations **Areas of application:** **a. Pure self-curing of Adhese 2 only in combination with VivaPen DC cannulas and DC applicators** – Adhesive cementation of indirect restorations and endodontic posts using Variolink® Esthetic DC in combination with all etching techniques. – Adhesive cementation of indirect restorations and endodontic posts using light- and dual-curing luting composites in combination with the etch & rinse technique. **b. Light-curing of Adhese 2 at 500 to 1400 mW/cm2 (10 seconds) or at 1800 to 2200 mW/cm2 (5 seconds)** – Adhesive cementation of indirect restorations with light- and dual-curing luting composites – Directly placed reconstructive build-ups and core build-ups made with light-, self- and dual-curing composites – Directly placed light-curing composite and compomer restorations – Repair of fractured composite and compomer restorations – Desensitization of hypersensitive cervical areas (Note: Provide additional cooling with an air syringe when applying the product.) – Sealing of prepared tooth surfaces before temporary/permanent cementation of indirect restorations **c. Light-curing of Adhese 2 using Bluephase PowerCure in the 3sCure curing mode** – Only restorations in the posterior region of permanent dentition (Class I and II, including the replacement of individual cusps) when light-cured from the occlusal aspect.	☒	☐

Precaution Measures/ Contraindications / Processing restrictions/ Side effects	**Contraindications:** Do not use Adhese Universal DC if the patient is known to be allergic to any of the materials' ingredients or if the stipulated working technique cannot be employed. **Limitations for use:** – Direct pulp capping – Do not use Adhese Universal DC as a primer for ceramic restorative materials. A suitable ceramic primer must be used (e.g. Monobond Etch & Prime).	**Contraindication** – The use of the product is contraindicated if the patient is known to be allergic to any of its ingredients. – Direct pulp capping **Limitations of use** – Do not use Adhese 2 as a primer for ceramic restorative materials. In such cases, suitable ceramic primers must be used. – Adhese 2 must not be used if the stipulated working technique cannot be employed.	☐	☒
Summary of Indications, Precaution Measures/ Contraindications / Processing restrictions/ Side effects	Both products are dental adhesives. The indications and contraindications are basically the same. The area of application has been added for the new device Adhese 2 under section "indication" to clarify how the new adhesive can be used with which light-intensities. Therefore, the products are substantially equivalent			
Working Principle	Adhese Universal DC is a dual-curing, single component dental adhesive for enamel and dentin that is compatible with all etching techniques (self-etch, selective enamel-etch, etch & rinse techniques). The areas of application include adhesive cementation of indirect restorations and direct restorative procedures. Adhese Universal DC is available in bottles and Free Stand Single Dose units. The applicator is coated with co-initiators required for the self-curing reaction. The initiator and adhesive are mixed together by dipping the applicator into the single dose unit containing the liquid Adhese Universal DC.	Adhese 2 is a dual-curing single-component dental adhesive for enamel and dentin that is compatible with all etching techniques (self-etch, selective-enamel etch and etch & rinse techniques). The areas of application include adhesive cementation of indirect restorations and direct restorative procedures. Adhese 2 is available in the VivaPen, in bottles or in Free Stand Single Dose units. The applicator is coated with co-initiators required for the self-curing reaction. The initiator and adhesive are mixed together by dipping the applicator into the single dose unit containing the liquid Adhese 2. To enable the function for the VivaPen, the cannulas adapted to the VivaPen are coated with the initiator.	☒	☐
Summary of Working Principle	As Adhese 2 is also available in the VivaPen, cannulas coated with the initiator are required. This application form (VivaPen) is new compared to the predicate device Adhese Universal DC. However, there are no significant differences. Therefore, both devices are considered to be substantially equivalent.			
Delivery forms/dosage	Single Dose 0.1 g Bottle with 6 g with a separate brush	VivaPen 0.5ml, 2 ml Single Dose 0.1 g Bottle 6g	☒	☐
Summary of Delivery forms/dosage	The new device Adhese 2 is also available in the VivaPen in addition to the single dose and bottle compared to the predicate Adhese Universal DC. To enable the function for the VivaPen, the cannulas are coated with the initiator vanadyloxalat. However, there are no significant differences and the products are considered to be substantially equivalent.			
Storage Conditions	24 months at 2-28 °C / 36-82 °F	24 months at 2-28 °C / 36-82 °F	☐	☒
Summary of Storage Conditions	No difference.			
Principles of Operation	**Step-by-step application:** 1. Isolation 2. Pulp protection/cavity liner 3. Conditioning with phosphoric acid gel 4. Activation of the Free Stand Single Dose	**Step-by-step application:** 1. Isolation 2. Pulp protection/cavity liner 3. Conditioning with phosphoric acid gel	☐	☒

	5. Application of the Adhesive 6. Curing the adhesive 7. Application of the restorative or luting composite				4. Handling of the VivaPen, bottle and Free Stand Single Dose unit 5. Application of the adhesive 6. Application of the restorative or luting composite				
Summary Principles of operation	No difference.								
Summary of Chemical Composition	The chemical composition slightly differs between Adhese Universal DC and the new device Adhese 2. The results of the Biocompatibility Assessment for Adhese 2 is substantially equivalent to the results of the Biocompatibility Assessment for the predicate device Adhese Universal DC.								
Finished Device Specification	Applicable Standards: *EN 1641:2009 – Dentistry – Medical devices for dentistry – Materials* *ISO 29022 – Dentistry – Adhesive – Notched-edge sheer bond strength test*				Applicable Standards: *EN 1641:2009 – Dentistry – Medical devices for dentistry – Materials* *ISO 29022 – Dentistry – Adhesive – Notched-edge sheer bond strength test*			☐	☐
Summary of Finished Device Specification	No difference.								
Device Specification	Performance	Value		Unit	Value		Unit		
	Specification Adhesion	---	---	---	Shear bond strength (on Dentin) light-curing (LC)	≥ 25	MPa	☐	☒
		Shear bond Strength (Dentin) self curing	≥ 20	MPa	Shear bond strength (on Dentin) dual-curing (DC)	≥ 20	MPa	☒	☐
Summary of Performance Specification	The specification for the new device Adhese 2 and the predicate show the same specification for the self-curing/dual-curing mode. The specification for shear bond strength LC for Adhese 2 is higher (25 MPa) as the light-curing mode generally shows higher values. The specification for both devices is substantially equivalent.								
Sterilization	Not applicable. No sterilization recommendation.				Not applicable. No sterilization recommendation.			☐	☒
Single use	Consumable material				Consumable material			☐	☒

Substantial Equivalence to the predicate:

The indications of Adhese Universal and Adhese Universal DC are basically the same regarding the curing times for adhese 2. The biocompatibility of the new formulation was fully assessed and is substantially equivalent to Adhese Universal DC. The device performance was tested according to ISO 29022:2013 and was found to meet the relevant performance criteria.

Therefore, Adhese 2 is substantially equivalent to the predicate device.

Differences:

Indication differs in that Adhese 2 indications include additional information regarding the curing times.

The Working Principle is the same for both devices, but as Adhese 2 is also available in the VivaPen, cannulas coated with the initiator are required. This application form (VivaPen) is new compared to the predicate device Adhese Universal DC. However, there are no significant differences.

Adhese 2 is available in the VivaPen Delivery forms/dosage that the predicate device is not available in. To enable the function for the VivaPen, the cannulas are coated with the initiator vanadyloxalat. However, there are no significant differences, and the products are considered to be substantially equivalent.

The Chemical Composition in Adhese 2 is slightly different, but the biocompatibility of the new formulation was assessed and is substantially equivalent to Adhese Universal DC.

The device specification for shear bond strength LC for adhese 2 is higher (25 MPa) as the light-curing mode generally shows higher values.

Non-clinical performance testing:

Bench testing was performed to test the physical properties included in the Finished Device Specification for the subject device including: Shear bond strength according to EN ISO 29022:2013 Dentistry – Adhesion- Notched-edge shear bond strength test

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.

The product under assessment **Adhese 2** has no clinical cytotoxic risk, holds no potential for material-mediated pyrogenicity, presents no risks for acute, sub-acute, sub-chronic or chronic toxicity, is not an inducer of adverse implantation effects, is not genotoxic, is not carcinogenic, and is not causing reproductive and development toxicity.

While Adhese 2 can cause irritation and sensitization mostly likely in its unpolymerized state. If proper safety measures (according to the IFU) during handling and use are employed, health risks can be avoided.

The products do not represent a toxicological risk for the patient and the user.

On the basis of the toxicological evaluation of the products 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.

Conclusion:

Adhese Universal DC and the new device **Adhese 2** are both dental adhesives. The main difference between the two is that Adhese 2 is available in the VivaPen beside the delivery forms single dose and bottle. In addition, the recipe is slightly changed for the new device.

Therefore, **Adhese 2** is substantially equivalent to the predicate device, Adhese Universal DC.