June 7, 2022

Ivoclar Vivadent, AG
% Lori Aleshin
Director of Quality & Regulatory Affairs
Ivoclar Vivadent, Inc
175 Pineview Drive
Amherst, New York 14228

Re: K210804
Trade/Device Name: Adhese Universal DC, Cention Primer
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: Class II
Product Code: KLE, LBH
Dated: March 5, 2022
Received: March 10, 2021

Dear Lori Aleshin:

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)*
K210804

Device Name
Adhese® Universal DC

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

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) SUMMARY

Adhese Universal DC- K210804

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Date Prepared: May 5, 2022

Proprietary Name: **Adhese® Universal DC (K210804)**

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

Secondary Classification Name: Varnish, Cavity (872.3260)
(Classification Code LBH)

Predicate Device: Adhese Universal (K133318) by Ivoclar Vivadent, AG

Device Description: **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 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.

Indications for Use:

- Missing tooth structure
- Defective restorations

Comparison to Predicate: The primary predicate device to which Adhese Universal DC has been compared is Ivoclar Vivadent, AG Adhese Universal (K133318).

	Predicate Device:	Proposed Device:	Deviation	
Device	**Ivoclar Vivadent AG: Adhese Universal (K133318)**	**Ivoclar Vivadent AG: Adhese Universal DC (K210804)**	**Yes**	**No**
Indications for Use	– Direct-placed light-curing composite and compomer restorations. – Direct-placed core build-ups with light-, self- and dual-curing composites. – Repairs of fractured composite and compomer restorations. – Adhesive cementation of indirect restorations with light- and dual-curing luting composites. – Sealing of prepared tooth surfaces before temporary / permanent cementation of indirect restorations. – Desensitization of hypersensitive cervical areas.	– Missing tooth structure – Defective restorations	☒	☐
Precaution Measures/ Contraindications/ Processing restrictions/ Side effects	**Contraindication** – Do not use Adhese Universal if the patient is known to be allergic to any of the materials' ingredients or if the stipulated working technique cannot be employed. – Applications in which sufficient illumination cannot be ensured (e.g. cementation of root canal posts). – Direct pulp cappings.	**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).	☐	☒
Summary of Indications, Precaution Measures/ Contraindications/ Processing restrictions/ Side effects	In the Instructions for Use for the predicate Adhese Universal the application of the medical device was assigned as "indications." According to the official definition of indications as clinical conditions, the list of indications was updated in the IfU for Adhese Universal DC. The applications are still part of the IfU under section "Description": Adhese Universal DC covers the same application as Adhese Universal. The contraindications are basically the same.			
Working Principle	Adhese Universal is a light-curing single-component dental adhesive for enamel and dentin and is compatible with all etching techniques (self-etch, selective-enamel-etch and etch & rinse techniques).	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 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.	☒	☐
Summary of Working Principle	The main difference between Adhese Universal and Adhese Universal DC is that the new device is dual curing in comparison to the predicate which can be cured with light only.			

Delivery forms/dosage	Bottle of liquid 5g Vivapen 0.5 ml and 2 ml	Single Dose 0.1 g Bottle 6 g with a separate brush	☒	☐
Summary of Delivery forms/dosage	Single doses and bottle available; difference in the amount only;			
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:** 1. Isolation 2. Pulp protection/cavity liner 3. Conditioning with phosphoric acid gel (optional) 4. Handling VivaPen and bottle 5. Application of the adhesive 6. Light-curing the adhesive 7. Application of the restorative or luting composite	**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 5. Application of the Adhesive 6. Curing the adhesive 7. Application of the restorative or luting composite	☒	☐
Summary Principles of operation	Basically, the step-by-step application is the same for both devices.			
Chemical Composition	Methacrylates, ethanol, water, highly dispersed silicon dioxide, initiators and stabilizers	HEMA, MDP, Bis-GMA, D3MA, ethanol, methacrylate-modified polyacrylic acid, silicon dioxide, potassium hydroxide and camphorquinone.	☒	☐
Summary of Chemical Composition	The chemical composition slightly differs between Adhese Universal and Adhese Universal DC, as the new device is dual curing. The results of the Biocompatibility Assessment for Adhese Universal DC is substantially equivalent to the results of the Biocompatibility Assessment for the predicate device Adhese Universal.			
Finished Device Specification	EN 1641:2009- Dentistry – Medical devices for dentistry – Materials ISO 29022- Dentistry – Adhesive – Notched-edge sheer bond strength test	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.			
Sterilization	Not applicable. No sterilization recommended.	Not applicable. No sterilization recommended.	☐	☒
Single use	Consumable material	Consumable material	☐	☒
Performance-Specification Adhesion	Shear bond strength (Dentin): ≥25 MPa	Shear bond strength (Dentin) ≥20 MPa Self-curing	☒	☐
Summary of Performance Specification	The specification for Adhese Universal DC describes lower values (20 MPa) for shear bond strength (dentin) compared to Adhese Universal (25 MPa) due to the self-curing mode of Adhese Universal DC which generally shows lower values. These values are comparable to the specification of Adhese Universal.			
Biocompatibility	evaluated for Biocompatibility according to ISO 10993-1:2018, ISO 7405:2018 and ISO 14971:2012	evaluated for Biocompatibility according to ISO 10993-1:2018, ISO 7405:2018 and ISO 14971:2012	☐	☒
Discussion of Biocompatibility	The results of the Biocompatibility Assessment for Adhese Universal DC is substantially equivalent to the results of the Biocompatibility Assessment for the predicate device Adhese Universal.			

Substantial Equivalence to the predicate:
Adhese Universal and Adhese Universal DC are both dental adhesives. The main difference between the two devices is that Adhese Universal is light-curing compared to Adhese Universal DC which is dual-curing. Therefore, Adhese Universal DC is substantially equivalent to the predicate device, Adhese Universal.

Differences:
The main difference between Adhese Universal and Adhese Universal DC is that the new device is dual-curing compared to the light-curing Adhese Universal. As the new device is dual-curing the chemical composition has been slightly adapted for Adhese Universal DC.

Non-clinical performance testing:
Bench testing was performed to test the physical property (shear bond strength) included in the Finished Device Specification for the subject device according to EN ISO 1641:2009 – Dentistry- Medical devices for dentistry – Materials and ISO 29022- Dentistry – Adhesive – Notched-edge sheer bond strength test.

Biocompatibility:
The subject device was also evaluated for Biocompatibility according to ISO 10993-1:2018, ISO 7405:2018 and ISO 14971:2012. Uncured Adhese Universal as well as extracts of polymerized Adhese Universal DC possess a cytotoxic potential in the XTT assay. The clinical experience with a previous generation of the product (Adhese Universal) indicates no adverse effect in clinical use. The product, particularly in the uncured state may cause sensitization against methacrylates. This is typical for all resin-based dental materials. On the basis of the clinical experience with a previous generation of the product it can be concluded that the products do not cause oral mucosal or gingival irritation. There is no material mediated pyrogenicity. According to the information available, the product have no acute nor subacute system toxicity. Subchronic or chronic toxicity is not expected. According to the data available Adhese Universal DC is not genotoxic nor carcinogenic. According to the current knowledge, it can be concluded that Adhese Universal DC does not cause adverse reactions upon implantation in teeth. Adhese Universal DC are expected not to cause pulp or dentine damage. There is no indication that toxic degradation products might be released during body contact.

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 results of the Biocompatibility Assessment for Adhese Universal DC is substantially equivalent to the results of the Biocompatibility Assessment for the predicate device Adhese Universal.

Conclusion:
Adhese Universal and Adhese Universal DC are both dental adhesives. The main difference between the two devices is that Adhese Universal is light-curing compared to Adhese Universal DC which is dual-curing. The indications / contraindications are basically the same. The device performance is substantially equivalent. The biocompatibility and storage stability of the new formulation was fully assessed and is substantially equivalent to Adhese Universal.

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