June 15, 2022

Diadent Group International
Kab Lee
Quality Assurance Manager
16, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu
Cheongju-si, Chungcheongbuk-do 28161
SOUTH KOREA

Re: K220804
Trade/Device Name: Dia-X Bond Universal
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: Class II
Product Code: KLE
Dated: May 11, 2022
Received: May 16, 2022

Dear Kab Lee:

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)*
K220804

Device Name
Dia-X Bond Universal

Indications for Use *(Describe)*
- All direct restorations
- All indirect restorations
- Desensitizing/sealing of tooth
- Intra-oral repairs

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Diadent Group International

Special 510(k) Summary

1 Application Information

Date Prepared:	May 11, 2022
Company Name and Address:	DiaDent Group International 16, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28161, Republic of Korea
Contact Person:	Kab Sun, Lee Quality Assurance Manager Phone: +82-43-266-2315 FAX: +82-43-235-2315 Email: diadent32@diadent.co.kr

2 Device Information

510(k) Number	**K220804**
Classification Name	Agent, Tooth Bonding, Resin
Common Name	Resin tooth bonding agent.
Review Panel:	Dental
Regulation Number:	21 CFR 872.3200
Product Code:	KLE
Device Class:	II
Trade Name	Dia-X Bond Universal

3 Predicate Devices

The legally marketed devices to which substantial equivalence is being claimed are:

	Primary Predicate Device
510(k) Number:	K213401
Applicant:	DiaDent Group International
Device Name:	DIAPLUS Universal
Regulation Number:	21 CFR 872.3200
Product Code:	KLE
Device Class:	II

4 Device Configuration

Dia-X Bond Universal: 1 bottle (5ml, 1ml)

5 Device Description

Dia-X Bond Universal is a universal adhesive capable of total, self, and selective etching as it consists of a single bottle of etching, primer, and adhesive resin. It can be used for both direct and indirect bonding of restorations.

6 Intended Use/Indications for Use

- All direct restorations
- All indirect restorations
- Desensitizing/sealing of tooth
- Intra-oral repairs

7 Comparison Table and Discussion

This device compares to the legally marketed devices as follows:

	Subject Device	**Primary Predicate Device**	
Common name	Resin tooth bonding agent.	Resin tooth bonding agent.	
Trade Name	**Dia-X Bond Universal**	**DIAPLUS Universal**	**Discussion**
510(k) Number	**K220804**	K213401	-
Indication for Use	- All direct restorations - All indirect restorations - Desensitizing/sealing of tooth - Intra-oral repairs	- All direct restorations - All indirect restorations - Desensitizing/sealing of tooth - Intra-oral repairs	Equivalent
Composition	- 10-methacryloyloxydecyl dihydrogenphosphate - 2-Hydroxyethyl methacryalate - Bis[2-(methacryloyloxy)ethyl] phosphate - 3-(Trimethoxysilyl)propyl methacrylate - Trimethylolpropane trimethacrylate - BisGMA/TEGDMA Monomer Blend - Poly(ethylene glycol) dimethacrylate - Diphenyliodonium hexafluorophosphate -. Phenyl Bis(2,4,6-Trimethylbenzoyl)phosphineoxide - (+/-)Camphorquinone - Ethyl 4-dimethyl aminobenzoate - tert-butyl hydroquinone - Ethyl alcohol - Silicon dioxide	- 10-methacryloyloxydecyl dihydrogenphosphate - 2-Hydroxyethyl methacryalate - Bis[2-(methacryloyloxy)ethyl] phosphate - 3-(Trimethoxysilyl)propyl methacrylate - Trimethylolpropane trimethacrylate - BisGMA/TEGDMA Monomer Blend - Poly(ethylene glycol) dimethacrylate - Diphenyliodonium hexafluorophosphate -. Phenyl Bis(2,4,6-Trimethylbenzoyl)phosphineoxide - (+/-)Camphorquinone - Ethyl 4-dimethyl aminobenzoate - tert-butyl hydroquinone - Ethyl alcohol - Silicon dioxide	Equivalent
Principle of operation	After being applied to the tooth surface, the solvent is volatilized and photopolymerized in the drying process to perform the function as a dentin adhesive. The main material, MDP contains a hydrophobic long carbon chain and a hydrophilic phosphate group, so it has excellent surface activity and can easily permeates dentin & enamel. It increases bonding to hydroxyapatite remaining in dentin.	After being applied to the tooth surface, the solvent is volatilized and photopolymerized in the drying process to perform the function as a dentin adhesive. The main material, MDP contains a hydrophobic long carbon chain and a hydrophilic phosphate group, so it has excellent surface activity and can easily permeates dentin & enamel. It increases bonding to hydroxyapatite remaining in dentin.	Equivalent
Performance Standard Conformance	Conformed ISO 4049 and ISO 29022	Conformed ISO 4049 and ISO 29022	Equivalent
Physical properties	- Film thickness - Sensitivity to light - Shear bond strength - Occlusion of dental tubules	- Film thickness - Sensitivity to light - Shear bond strength - Occlusion of dental tubules	Equivalent
Biocompatibility	Biocompatible	Biocompatible	Equivalent
Package Contents	One bottle	One bottle	Equivalent
RX only/ OTC	RX Only	RX Only	Equivalent

8 Non-Clinical performance data

This device has demonstrated conformance with non-clinical performance requirements through evaluation and testing in accordance with the following harmonized standards:

-ISO 4049	Dentistry -- Polymer-based restorative materials
-ISO 7405	Dentistry - Evaluation of Biocompatibility of Medical Devices Used In Dentistry [Including: Amendment 1 (2013)]
-ISO 29022	Dentistry - Adhesive - Notched-edge sheer bond strength test
-ISO 10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
-ISO 10993-3	Biological evaluation of medical devices - Part 3: Tests for genotoxicity carcinogenicity and reproductive toxicity
-ISO 10993-5	Biological evaluation of medical devices - Part 5: Tests for in vitro Cytotoxicity
-ISO 10993-10	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
-ISO 10993-11	Biological evaluation of medical devices – Part 11: Tests for Systemic toxicity

The following Performance tests were conducted.

- Film Thickness
- Shear Bonding Strength
- Sensitivity to Ambient Light
- Occlusion of dentinal tubules

Biocompatibility test:

Test	**Standard**	**Test result**
Cytotoxicity Study	•10993-5 – Biological Evaluation of Medical Devices – Part 5: Tests for In Vitro Cytotoxicity	**Not Compatible BSE**
Bacterial Reverse Mutation Study	•10993-3 – Biological Evaluation of Medical Devices – Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity	**Compatible**
In vitro Mammalian Chromosomal Aberration Test	•10993-3 – Biological Evaluation of Medical Devices – Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity	**Compatible**
Mammalian Erythrocyte Micronucleus	•10993-3 – Biological Evaluation of Medical Devices – Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity	**Compatible**
Skin Sensitization Test	•10993-10 – Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization	**Compatible**
Oral Mucosa Irritation Test	•10993-10 – Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization	**Compatible**
Acute Systemic Toxicity	•10993-11 – Biological Evaluation of Medical Devices – Part 11: Tests for Systemic Toxicity	**Compatible**

(Among the components of this product, 10-MDP is an acidic monomer, and depending on the acidity, it is a substance that causes cytotoxicity according to the principle of action of this product, so cytotoxicity test setting the test item is meaningless.

9 Clinical Performance Data

No clinical data was collected or provided to support substantial equivalence between the subject and predicate devices.

10. Conclusion

Based on the above information and all data provided in this submission, the comparison of intended uses, technological characteristics, and non-clinical performance testing demonstrates that the subject device is substantially equivalent to the legally marketed devices identified in this submission.