May 26, 2020

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

Re: K192392
Trade/Device Name: DiaPlus
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: Class II
Product Code: KLE
Dated: February 21, 2020
Received: February 27, 2020

Dear Kab Sun 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,

for Srinivas “Nandu” Nandkumar, Ph.D.
Director
DHT1B: Division of Dental 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192392

Device Name
DIAPLUS

Indications for Use *(Describe)*
As a dentine/enamel total etching bonding system for direct adhesion, it is used in the adhesion of all direct restoration substances.
- Bonding of direct composite
- Bonding to composite and set amalgam
- Bonding of indirect restoration-Porcelain, Composite (Inlays, Onlays, Veneers, Crowns)

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

510(k) Summary

1 Application Information

Date Prepared: May 25 2020

Manufacturer:

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

Device Type:	Agent, Tooth Bonding, Resin
Regulation Description:	Resin tooth bonding agent.
Review Panel:	Dental
Regulation Number:	21 CFR 872.3200
Product Code:	KLE
510(k) Number	K192392
Device Class:	II
Device Name:	DIAPLUS

3 Predicate Devices

510(k) Number:	K043562 (Primary Predicate)
Applicant:	VERICOM Co., Ltd.
Device Name:	BC Plus
Regulation Number:	872.3200
Product Code:	KLE
Device Class:	Class II

4 Products configuration

DiaPlus : 1 bottle (5ml)

5 Device Description

DiaPlus is a photopolymerization type dentine and enamel adhesive as a 5th generation dentine adhesion system that can be applied to all types of composite resin restorations.

6 Indications for Use

As a dentine/enamel total etching bonding system for direct adhesion, It is used in the adhesion of all direct restoration substances.

- Bonding of direct composite
- Bonding to composite and set amalgam
- Bonding of indirect restoration-Porcelain, Composite (Inlays, Onlays, Veneers, Crowns)

7 Substantial Equivalence discussion

<Comparison table>

	Subject Device	Primary predicate Device	Discuss
Product name	DiaPlus	BC Plus	
Manufacturer	DiaDent Group International	VERICOM Co., Ltd.	
510K Number	K192392	K043562	
Product Code	KLE	KLE	
Device Description	DiaPlus is a photopolymerization type dentine and enamel adhesive as a 5th generation dentine adhesion system that can be applied to all types of composite resin restorations.	BC Plus is a single component bonding agent designed to bond composite to dentin, enamel, cast metals, treated porcelain and set amalgam. BC Plus is an ethanol based formulation of light-activated, adhesive resin.	
Indications for Use	As a dentine/enamel total etching bonding system for direct adhesion, it is used in the adhesion of all direct restoration substances. - Bonding of direct composite - Bonding to composite and set amalgam - Bonding of indirect restoration-Porcelain, Composite (Inlays, Onlays, Veneers, Crowns)	BC Plus is a light curing single component bonding agent use in restorative adhesive dentistry specifically developed for bonding resin-based filling materials (e.g. composite, compomers) to hard dental tissues. Other indications include bonding of amalgam and laboratory-produced restorations. BC Plus permits priming and bonding to be carried out in single step	
Chemical Composition	- Ethanol - UDMA (Urethane Dimethacrylate) - BisGMA (bisphenolA-glycidyl methacrylate) -TEGDMA (Triethylene glycol dimethacrylate) - HEMA succinate - Champhor quinone	- Ethanol - BisGMA (bisphenolA-glycidyl methacrylate) - HEMA ((Hydroxyethyl)methacrylate) - Champhor quinone	

Principle of operation	Light cured	Light cured	equivalent
Physical and Mechanical properties	Conformed in accordance with ISO 4049 -Bonding strength -Depth of cure -Sensitivity to ambient light	Conformed in accordance with ISO 4049 Bonding strength Depth of cure	equivalent
Bonding Agent Type	5th generation bonding agent (Primer & Adhesive combined in one bottle)	5th generation bonding agent (Primer & Adhesive combined in one bottle)	equivalent
Biocompatibility	Yes ISO 10993-1 :2009	Yes ISO 10993-1 :2009	equivalent
RX Only/ OTC	RX Only	RX Only	equivalent

- Indication for use

	Subject device (DiaPlus)	Primary Predicate Device (BCPlus)
Description	DiaPlus is a photopolymerization type dentine and enamel adhesive as a 5th generation dentine adhesion system that can be applied to all types of composite resin restorations.	BC Plus is a single component bonding agent designed to bond composite to dentin, enamel, cast metals, treated porcelain and set amalgam. BC Plus is an ethanol based formulation of light-activated, adhesive resin.
Indication For Use	As a dentine/enamel total etching bonding system for direct adhesion, it is used in the adhesion of all direct restoration substances. - Bonding of direct composite - Bonding to composite and set amalgam - Bonding of indirect restoration-Porcelain, Composite (Inlays, Onlays, Veneers, Crowns)	BC Plus is a light curing single component bonding agent use in restorative adhesive dentistry specifically developed for bonding resin-based filling materials (e.g. composite, compomers) to hard dental tissues. Other indications include bonding of amalgam and laboratory-produced restorations. BC Plus permits priming and bonding to be carried out in single step

Discussion:

DiaPlus and BCPlus are photopolymerization type dentine and enamel adhesive using light curing.

The indication for Use of both devices are direct composite and indirect restorationIt seems that the indication of use are similar.

- Raw material

Subject device (DiaPlus)	Primary Predicate Device (BCPlus)
- Ethyl alcohol - UDMA (Urethane Dimethacrylate) - BisGMA (bisphenolA-glycidyl methacrylate) -TEGDMA (Triethylene glycol dimethacrylate) - HEMA succinate - Champhor quinone	- Ethyl alcohol - BisGMA (bisphenolA-glycidyl methacrylate) -HEMA((Hydroxyethyl)methacrylate) - Champhor quinone

Discussion :

The predicate device is composed of Solvent, resin, primer, Photoinitiator for light curing as does the subject device. Results of bench and biocompatibility testing completed in alignment with ISO 4049 and ISO 10993-1, respectively demonstrate that any material differences between the subject device and predicate device do not raise any new questions as to safety and effectiveness. Therefore, it is concluded that DiaPlus is substantially equivalent to the predicate device.

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/TS 11405	Dentistry - Testing of adhesion to tooth structure
-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 1:Evaluation and testing within a risk management process
-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
- Depth of cure
- Sensitivity to ambient light
- Bond strength (Enamel/Dentin)
- Bond strength (Metal/Veneer)
- Dentinal tubule occluding property
- Biocompatibility test

Biocompatibility test:

Test	Standard	Test result
Cytotoxicity Study	•10993-5 – Biological Evaluation of Medical Devices – Part 5: Tests for In Vitro Cytotoxicity	**Pass**
Sensitization Test	•10993-10 – Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization	**Pass**
Oral Mucosa Irritation Test	•10993-10 – Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization	**Pass**
Acute Systemic Toxicity	•10993-11 – Biological Evaluation of Medical Devices – Part 11: Tests for Systemic Toxicity	**Pass**

9 Clinical Performance Data

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

10 Conclusions

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.