February 7, 2020

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

Re: K192273
Trade/Device Name: DIAETCH Economic Package Type A, DIATECH Regular Package, DIAETCH Refill Package Type A, DIAETCH Intro Kit
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: Class II
Product Code: KLE
Dated: August 1, 2020
Received: August 1, 2020

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,

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)*
K192273

Device Name
DIAETCH

Indications for Use *(Describe)*
DiaEtch is a 37% phosphoric acid etchant used for etching enamel and dentin to promote adhesion of primer/bonding agent adhesives to tooth structure and restorative materials.

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

1 Application Information

Date Prepared:	February 6, 2020
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

Device Type:	Agent, Tooth Bonding, Resin
Regulation Description:	Resin tooth bonding agent.
Review Panel:	Dental
Regulation Number:	21 CFR 872.3200
Product Code:	KLE
Device Class:	II
Device Name:	DIAETCH

3 Predicate Devices

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

	Primary Predicate Device	**Reference Predicate Device**
510(k) Number:	K112597	K172953
Applicant:	MYCONE DENTAL SUPPLY CO., INC.	American Orthodontics
Device Name:	seity 37% Phosphoric Acid Etching Gel	Acid Etchant
Regulation Number:	21 CFR 872.3200	21 CFR 872.3200
Product Code:	KLE	KLE
Device Class:	II	II

4 Products configuration

Each models of subject device configuration is described as following:

Model Name	Product Configuration
Economic Package Type A	Syringes with 5ml of products x 5ea Disposable tips x 20ea
Regular Package	Syringes with 3ml of products x 2ea Disposable tips x 10ea
Refill Package Type A	Syringes with 5ml of products x 1ea Disposable tips x 5ea
Intro Kit	Syringes with 3ml of products x 1ea Disposable tips x 2ea

5 Device Description

Blue colored gel-type substance containing 37% phosphoric acid that corrodes enamel and dentine.

6 Indications for Use

DiaEtch is a 37% phosphoric acid etchant used for etching enamel and dentin to promote adhesion of primer/bonding agent adhesives to tooth structure and restorative materials

7. Substantial Equivalence

	Subject Device	**Primary Predicate Device**	**Reference Predicate Device**
Product name	**DiaEtch**	Seity 37% Phosphoric Acid Etching Gel	Acid Etchant
Manufacturer	DiaDent Group International	Mycone Dental	American Orthodontics
510K Number	-	K112597	K172953
Product Code	KLE	KLE	KLE
Indications For Use	DiaEtch is a 37% phosphoric acid etchant used for etching enamel and dentin to promote adhesion of primer/bonding agent adhesives to tooth structure and restorative materials	A thixotropic 37% phosphoric acid dental etchant gel for etching enamel, dentin, and glass ionomer cements to produce the necessary micro-retentive surface for successful bonding of restorations.	Acid Etchant is a phosphoric acid etchant used for etching enamel and dentin to promote adhesion of primer/bonding agent adhesives to tooth structure and restorative materials.

Material Composition	-. Phosphoric acid 37% -. Water -. Citric acid anhydrous -. Silicone dioxide -. Xanthan Gum -. Ethyl alcohol -..Colorant	-. Phosphoric acid 37%	-. Phosphoric acid 25~50% -. Water -. Silicon Dioxide -. Surfactants -. Blue colorant
Device description	Thixotropic dental etchant gel with 37% phosphoric acid	Thixotropic dental etchant gel with 37% phosphoric acid	Thixotropic dental etchant gel with 37% phosphoric acid
Physical and Mechanical Properties	-. Ph : 1.4±0.2 -. Viscosity : 60,000cps -. Consistency : Thick gel -. Color : Blue or dark blue	-. pH : 1.52 -. Viscosity : 60,000cps -. Consistency : Thick gel -. Color : Blue or green	-. pH_<2 -. Consistency : Thick gel -. Color : Blue or green
Use	Prescription/Hospital	Prescription/Hospital	Prescription/Hospital
Delivery forms (Design)	Pre-filled syringe	Pre-filled syringes	Pre-filled syringe

- Indications For Use

Subject Device	Predicate Devices(K112597)	Predicate Devices(K172953)	Discussion
DiaEtch is a 37% phosphoric acid etchant used for etching enamel and dentin to promote adhesion of primer/bonding agent adhesives to tooth structure and restorative materials	A thixotropic 37% phosphoric acid dental etchant gel for etching enamel, dentin, and glass ionomer cements to produce the necessary micro-retentive surface for successful bonding of restorations.	Acid Etchant is a phosphoric acid etchant used for etching enamel and dentin to promote adhesion of primer/bonding agent adhesives to tooth structure and restorative materials.	The substance of the subject device is identical with the predicate devices (Substance is Thixotropic dental etchant gel with 37% phosphoric acid) and the main function of devices is to help improve adhesion of resin/restorations. Therefore, the Indication for use of the subject and predicate device is not significantly different and the safety and performance is not expected to be affected by these differences.

-Composition

Subject Device	Predicate Device(Primary)	Predicate Device(Reference)	Discussion
-. Phosphoric acid 37% -. Water -. Citric acid anhydrous -. Silicone dioxide -. Xanthan Gum -. Ethyl alcohol -..Colorant	-. Phosphoric acid 37% -. Water -. Additives	-. Phosphoric acid 25~50% -. Water -. Silicon Dioxide -. Surfactants -. Blue colorant	The main ingredient of subject and predicate devices is Phosphoric acid. and the functions of other additives are similar (base, thicker, surfactants, colorant). Also, the biocompatibility of subject device was confirmed by biological safety study.

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 7405	Dentistry - Evaluation Of Biocompatibility Of Medical Devices Used In Dentistry [Including: Amendment 1 (2013)]
-ISO 10993-1	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

The following Performance tests were conducted.

- pH
- Viscosity
- Density
- Biocompatibility test

Performance test (Physical properties):

Test	DiaEtch	Primary predicate device
pH	1.4 ±0.2	1.52
Viscosity	60,000 cps	60,000 cps
Density	1.2	

Biocompatibility test:

Test	**Standard**	**Test result**
Cytotoxicity	ISO 10993-5 - Biological evaluation of medical devices - Part 5. Tests for in vitro Cytotoxicity	**Pass**
Sensitization	ISO 10993-10 - Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization	**Pass**
Oral Mucosa Irritation	ISO 10993-10 - Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization	**Pass**

9. Conclusion

Based on the above information and all data provided in this submission, including comparison of intended uses, technological characteristics discussion of differences of subject and predicate devices, show that the subject device and the predicate device have similar technical characteristic and chemical composition.

It is demonstrated that the subject device and the legally marketed devices identified in this submission are substantially equivalent.