June 28, 2021

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

Re: K210421/S002
Trade/Device Name: Diafil & Diafil Capsule
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth shade resin material
Regulatory Class: Class II
Product Code: EBF, KLE
Dated: May 26, 2021
Received: June 1, 2021

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)*
K210421

Device Name
DIAFIL & DIAFIL CAPSULE

Indications for Use *(Describe)*

DiaFil & DiaFil Capsule
composite material which has resin organic and inorganic fillers or complex fillers as ingredients, which are being used for aesthetic restoration by getting polymerized directly in the oral cavity.
- Direct anterior and posterior 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.

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510(k) Summary - K210421

1 Application Information

Date Prepared:	February 8, 2021
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

	Subject Device
Device Name:	**DIAFIL & DIAFIL CAPSULE**
Device Type:	Tooth shade resin material
Regulation Number:	21 CFR 872.3690 21 CFR 872.3200
Regulation Description:	Material, Tooth Shade, Resin
Product Code:	EBF KLE
Device Class:	II

3 Predicate Devices

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

	Primary Predicate Device	**Predicate Device (Subsequent device 1)**	**Predicate Device (Subsequent device 2)**
Device Name:	**DIAFIL & DIAFIL CAPSULE**	**DIAPLUS**	**DIAETCH**
510(k) Number:	K192510	K192392	K192273
Applicant:	Diadent Group International	Diadent Group International	Diadent Group International
Regulation Number:	21 CFR 872.3690	21 CFR 872.3200	21 CFR 872.3200
Product Code:	EBF	KLE	KLE
Device Class:	II	II	II

4 Products configuration

The subject device is packaged with the following:

DiaFil Refill package	1 syringe of DiaFil (4g)
DiaFil Intro Kit	1 syringe of DiaFil (1g)
DiaFil Start Kit	5 syringes of DiaFil (4g each) A bottle of DiaPlus (5ml) A syringe of DiaEtch (3ml) Accessories
DiaFil Capsule type	20 capsule of DiaFil (0.25g)

5 Device Description

The product belongs to Group 1, Class 2 of Type 1 according to the standard classification of ISO 4049. It is a nano hybrid typed light-curved complex resin for aesthetic restoration for both anterior and posterior parts, which is used for restoration that requires aesthetics through decay and damage in a form of paste with unpolymerized dimethacrylate monomer, inorganic filler, and photoinitiators mixed. That is, after recovering with the unpolymerized product, to make a hard restoration by polymerizing through dental visible-ray polymerizer.

6 Indications for Use

DiaFil

A composite material which has resin organic and inorganic fillers or complex fillers as ingredients, which are being used for aesthetic restoration by getting polymerized directly in the oral cavity.
- Direct anterior and posterior restorations

DiaPlus (DiaFil Start Kit Component)

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

DiaEtch (DiaFil Start Kit Component)

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 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 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

Additional non-clinical bench testing demonstrates the safety and effectiveness of the subject device.

8 Substance Equivalence discussions

8.1 Comparison Table

This device compares to the legally marketed devices as follows:

	Primary Predicate Device (Original)	Predicate Device (Subsequent device 1)	Predicate Device (Subsequent device 2)	Subject Device
	DIAFIL & DIAFIL CAPSULE	**DIAPLUS**	**DIAETCH**	**DIAFIL & DIAFIL CAPSULE**
510(k) Number	K192510	K192392	K192273	K210421
Indication for Use	A composite material which has resin organic and inorganic fillers or complex fillers as ingredients, which are being used for aesthetic restoration by getting polymerized directly in the oral cavity. - Direct anterior and posterior restorations	As a dentine/enamel total etching bonding system for direct adhesion, it is used in the adhesion of all direction restoration substances. - Bonding of direct composite - Bonding to composite and set amalgam - Bonding of indirect restoration- Porcelain, Composite (Inlays, Onlays, Veneers, Crowns)	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.	DiaFil & DIAFIL CAPSULE: Same DiaPlus : Same DiaEtch : Same
Device Description	The product belongs to Group 1, Class 2 of Type 1 according to the standard classification of ISO 4049. It is a nano hybrid typed light-curved complex resin for aesthetic restoration for both anterior and posterior parts, which is used for restoration that requires aesthetics through decay and damage in a form of paste with unpolymerized dimethacrylate monomer, inorganic filler, and photoinitiators mixed. That is, after recovering with the unpolymerized product, to make a hard restoration by polymerizing	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. As a dentine/enamel total etching bonding system for direct adhesion, It is used in the adhesion of all direction restoration substances.	Thixotropic dental etchant gel with 37% phosphoric acid	DiaFil & DIAFIL CAPSULE: Same DiaPlus : Same DiaEtch : Same

	through dental visible-ray polymerizer.			
Construction	1) Refill package : 1 syringe of DiaFil (4g) 2) Intro Kit 1 syringe of DiaFil (1g) 3) Capsule type : 20 capsule of DiaFil (0.25g)	One bottle of DiaPlus(5ml)	1) Economic package 5 syringe of DiaEtch (5ml each) 20 disposable tips 2) Regular package 2 syringe of DiaEtch (3ml each) 10 disposable tips 3) Refill package 1syringe of DiaEtch(5ml) 5 disposable tips	Model addition : DiaFil Start Kit 5 syringes of DiaFil (4g each) A bottle of DiaPlus (5ml) A syringe of DiaEtch (3ml) Accessories : 50 brush tips 1 brush handle, A mixing well, A mixing pad, 10 disposable tips, A shade sheet.
Composition	- Bis-GMA - TEGDMA - UDMA - Barium-alumino-silicate - Silica - Pigments	- Ethanol - UDMA (Urethane Dimethacrylate) - BisGMA (bisphenolA-glycidyl methacrylate) -TEGDMA (Triethylene glycol dimethacrylate) - HEMA succinate - Champhor quinone	-. Phosphoric acid 37% -. Water -. Citric acid anhydrous -. Silicon dioxide, (chemically prepared) -. 1%-Methylene Blue solution -. Xanthan Gum -. Ethyl alcohol	DiaFil & DIAFIL CAPSULE: Same DiaPlus : Same DiaEtch : Same
Human factor	Ready to use dispensing system	Ready to use dispensing system	Ready to use dispensing system	DiaFil & DIAFIL CAPSULE: Same DiaPlus : Same DiaEtch : Same
Shelf life	3 years	2year	2year	DiaFil & DIAFIL CAPSULE: Same DiaPlus : Same DiaEtch : Same
Period of Use	Permanent (> 30 d)	Permanent (> 30 d)	-limited (≤24 h)	DiaFil & DIAFIL CAPSULE: Same DiaPlus : Same DiaEtch : Same
Biocompatibility	Conforming to ISO 10993-1	Conforming to ISO 10993-1	Conforming to ISO 10993-1	DiaFil & DIAFIL CAPSULE: Same DiaPlus : Same DiaEtch : Same
Performance Standard conformance	Meet ISO 4049 standard	Meet ISO 4049 standard	Meet ISO 4049 standard	DiaFil & DIAFIL CAPSULE: Same DiaPlus : Same DiaEtch : Same

8.2 Discussion :

The Change is only a package addition of DiaFil & DiaFil Capsule. The package includes 5th generation bonding agent (DiaPlus, K192392) and Etching agent (DiaEtch, K192273), which have already been proven to have Substantial product equivalence through the 510(k) decision of each product. The final package design of DIAFIL START KIT is added according to the configuration of package, but the products labeling of each components of package is not changed.

As the result of discussion of comparison, the package addition of DIAFIL & DIAFIL CAPSULE does not affect to the substantial equivalence of the original product.

9 Clinical Performance Data

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

10 Conclusions

Since the comparative products are components of the DiaFil &DIAFIL CAPSULE, the safety and effectiveness of subject product has already been proven in each approved product. According to the conclusion drawn from the comparison, the subject device is practically the same as the predicate devices that are legally sold in market.