March 25, 2020

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

Re: K192284
Trade/Device Name: DiaFil Flow
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth shade resin material
Regulatory Class: Class II
Product Code: EBF
Dated: December 26, 2019
Received: December 26, 2019

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)*
K192284

Device Name
DiaFil Flow

Indications for Use *(Describe)*
-Restoration of Class III, Class V, smaller Class IV
-Repair of resin, porcelain, and acrylic temporary materials
-Undercut blockout

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.

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510(k) Summary

This 510(k) summary on the safety and effectiveness information is submitted in accordance with the requirements of 21 CFR 807.92.

1. Application Information

Date Prepared	Mar 25,2020
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 Name	DiaFil Flow
510(k) Number	K192284
Classification Name	Tooth shade resin material
Review Panel	Dental
Regulation Number	21 CFR 872.3690
Product Code	EBF
Device Class	II

3. Predicate Devices

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

	Primary Predicate Device
510(k) Number:	K060637
Applicant:	VERICOM CO., LTD.
Device Name:	DENFIL FLOW
Regulation Number:	21 CFR 872.3690
Product Code:	EBF
Device Class:	II

4. Device Description

The subject device is a 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. The subject device is packaged with the following: Syringe, Disposable Tip, Protective Cap, Shade Sheet
Model Name: There are 57 models, and they are divided 19 types. (A1, A2, A2O, A3, A3O, A3.5, A4, B1, B2, B3, B4, C1, C2, C3, C4, D1, D2, D3, D4) These 19 types have differences in the pigment type and content (%).

Also, they (19 types) are packaged according to 3 forms: Economic, Refill, Intro Kit. The components of each package form are as follows.

	Components		
	Syringe	Disposable tips	Shade Sheet
Economic Package	2g x 4ea	40ea	1ea
Refill Package	2g x 1ea	10ea	N/A
Intro Kit	0.5g x 1ea	2ea	N/A

5. Indications for Use

-Restoration of Class III, Class V, smaller Class IV
-Repair of resin, porcelain, and acrylic temporary materials
-Undercut blockout

6. 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 4049:2009, Dentistry – Polymer-based restorative materials
•ISO 7405:2008, Dentistry – Evaluation of biocompatibility of medical devices used in dentistry
•ISO 10993-1:2009, Evaluation and testing within a risk management process
•ISO 10993-2:2006, Animal welfare requirements
•ISO 10993-3:2014, Tests for genotoxicity, carcinogenicity and reproductive toxicity
•ISO 10993-5:2009, Tests for in vitro cytotoxicity
•ISO 10993-6:2016, Tests for local effects after implantation
•ISO 10993-10:2010, Tests for irritation and skin sensitization
•ISO 10993-11:2017, Tests for systemic toxicity
•ISO 10993-12:2012, Sample preparation and reference materials

Through this additional non-clinical bench testing, the subject device is substantially equivalent to the predicate device.

7. Clinical Performance Data

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

8. Comparison with predicate Device

8.1 Comparison table

This device compares to the legally marketed devices as follows:

	Subject Device	**Primary Predicate Device**	**Discussion**
510(k) Number	-	K060637	
Applicant	DiaDent Group International	VERICOM CO.,LTD.	
Device Name	DiaFil Flow	DENFIL FLOW	
Indications for Use	•Restoration of Class III, Class V, smaller Class IV	•Class V restorations (Cervical caries, root erosion, wedge shaped defects)	See the below

	•Repair of resin, porcelain, and acrylic temporary materials •Undercut blockout	•Anterior restorations (Class Ⅲ, Ⅳ) •Small posterior restorations •Restorative therapy for mini-cavities of all types •Extended fissures sealings in molars and premolars •Repair of composite/ceramic veneers •Blocking out of undercuts	
Description	DiaFil Flow belongs to Group 1 of Class 2 of Type 1 according to the standard classification of ISO 4049. It is a light-curved complex resin for aesthetic restoration for both anterior and posterior parts. It is used for aesthetic restoration which is caused by decay and damage, and it is a paste form consisting of a mixture of unpolymerized dimethacrylate monomer, inorganic filler, and photoinitiators. That means that it makes a hard restoration by polymerizing through dental visible-ray polymerizer after recovering with the unpolymerized product.	DenFil Flow is a light-cured radio-opaque flowable restorative resin. It is composed of Epoxyacrylate (Bis-GMA), Diurethane dimethacrylate, Triethylenglycol dimethacrylate, Barium aluminosilicate, and other materials. As Denfil flow has a lower viscosity than paste type composite resin-Flow; 0.16 mm/30sec, so it can restore narrow & deep cavity easily. DenFil Flow can be applied to fill cavities of all types exactly and efficiently by using a disposable tip. And DenFil Flow has various shades that correspond to the most common used shading system.	Equivalent
Package Contents	•Syringe •Disposable Tip •Protective Cap •Shade Sheet	•Syringe •Disposable Tip •Protective Cap	Equivalent

Image			
Composition	•UDMA •Bis-EMA •TMPTMA •BKY-405 •Barium-alumino-silicate •Silica •Ytterbium •Camphorquinone •Ethyl-4-(Dimethylamino)benzoate(EDB) •BHT •2-Hydoxy-4-(octoxy)benzophenone	•UDMA •Bis-GMA •TEGDMA •Barium-alumino-silicate •Silica	See the below
Light curing time	20 seconds (If light curing unit output is below 400mW/cm2, as measured by a curing radiometer, more time may be needed.)	20 seconds (If light curing unit output is below 400mW/cm2, as measured by a curing radiometer, more time may be needed.)	Equivalent
Period of Use	Permanent	Permanent	Equivalent
Shelf life	3 years	3 years	Equivalent
Bio-compatibility	Biocompatible	Biocompatible	Equivalent
Standards	ISO7405	ISO7405	Equivalent

9. Differences

Indication for use

Subject Device	Primary Predicate Device
DiaFil Flow	DENFIL FLOW
Restoration of Class III, Class V, smaller Class IV	Class V restorations (cervical caries, root erosion, wedge shaped defects)
	Anterior restorations (Class III, IV)
	Small posterior restorations
Repair of resin, porcelain, and acrylic temporary materials	Restorative therapy for mini-cavities of all types
	Extended fissures sealings in molars and premolars
	Repair of composite/ceramic veneers
Undercut blockout	Blocking out of undercuts

The subject device has the same indications for use as the predicate device. The indications for use of the subject device is more simplified than the predicate device.

Material composition

Subject Device	Primary Predicate Device
DiaFil Flow	DENFIL FLOW
•UDMA •Bis-EMA •TMPTMA •BKY-405 •Barium-alumino-silicate •Silica •Ytterbium •Camphorquinone •Ethyl-4-(Dimethylamino)benzoate(EDB) •BHT •2-Hydoxy-4-(octoxy)benzophenone	•UDMA •Bis-GMA •TEGDMA •Barium-alumino-silicate •Silica

The main compositions are similar, but the compositions of DiaFil Flow and the predicate device are not same completely. However, DiaFil Flow and the predicate device are substantially equivalent through Biological Safety Assessment Report. (#BSA-2018-14)

The subject device has the similar technological characteristics as the predicate device; indications for use, main raw materials, mechanical properties (curing time, photopolymerization type resin).

ConClusions

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