March 20, 2020

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

Re: K192510
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
Dated: February 14, 2020
Received: February 20, 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)*
K192510

Device Name
DIAFIL & DIAFIL Capsule

Indications for Use *(Describe)*
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

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:	March 20, 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

Trade Name	DIAFIL & DIAFIL Capsule
Device Type:	Tooth shade resin material
Regulation Description:	Material, Tooth Shade, Resin
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:	K042124
Applicant:	Vericom
Device Name:	DenFil
Regulation Number:	21 CFR 872.3690
Product Code:	EBF
Device Class:	II

4.Products configuration

The subject device is packaged with the following:

Package type	**Components**
Refill Package	1 Syringe of product (4g)
Intro Kit	1 Syringe of Product (1g)
Capsule	1 Bottle (20capsules)

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

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

7.Comparison with Predicate Device

7.1 Comparison Table

This device compares to the legally marketed devices as follows:

	Subject Device	**Primary Predicate Device**
	DIAFIL & DIAFIL Capsule	**DENFIL**
	Diadent Group International	Vericom.Co., Ltd
510(k) Number	K192510	K042124
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.	DenFil™ is light-cured restorative hybrid composite resin and accessories for use in both posterior and anterior restoration..
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	DenFil™ is indicated for the following restorative applicantions; 1. Class I, II, V restorations of posterior teeth 2. Class III, IV, V restorations of anterior teeth 3. Cervical cavities or defects involving root surfaces

Diadent Group International

Image		
Composition	- Bis-GMA - TEGDMA - UDMA - Barium-alumino-silicate - Silica - Pigments	- Bis-GMA - TEGDMA - UDMA - Bis-EMA - Barium-alumino-silicate - Silica -Additives
Method of use	1) Select the shade Separate the area to be treated using rubber dam, etc. Wash the area. Select the appropriate shade.	1. Shade selection Clean teeth with pumice and water to remove surface stains or extraneous plaque. Teeth are not monochromatic. Consider shade and restoration depth. It is desirable to choose the shade after mocking up. Alternatively, Vita¹Lumin® Vacuum shade guide may be used. Using of rubber dam is recommended for isolation.
	2) Treat the decayed parts Remove amalgams or bases and foreign substances at the area to be treated that can be disturbing during the treatment	2. Cavity preparation – Anterior restoration Using the conventional acid etching, prepare cavity for all Class III, Class IV, and Class V restoration. – Posterior restoration Prepare the cavity. No residual amalgam or other base material should be left on the internal surfaces of preparation that would interfere with light transmission and the hardening of the restorative material.
	3) Pulp protection When the decayed part is deep, the pulp can be exposed. Therefore, according to the indicant, cap the pulp with calcium hydroxide and glass ionomer.	3. Pulp Protection In deep cavities cover the dentin close to the pulp with a minimum amount of calcium hydroxide liner leaving the rest of cavity surface free for bonding. Glass ionomer or other eugenol-free base materials may be used, if wished. 4. Placement of matrix Use a matrix system, preferably a transparent one, with proper wedging for proximal contracts. Pre-wedging is advocated to achieve slight separation and facilitate optimal proximal contact.

	4) Treatment of the enamel and the dentine For the pretreatment, according to the method of use of the products in use, operate acid etching and application of adhesive system in order.	5. Enamel and dentin treatment Follow the manufacturer's instructions regarding etching, priming, adhesive application and curing. It is recommended to use DenFil™Etchant-37 and BC Plus™or U-Bond™.
	5) Application -Open up the lid, take an adequate amount of the product out, and fill the resin at the area to be treated. Make sure to close the lid after use to prevent exposure to the light. (For the capsule type, you can directly restore the cavity using the dispenser. It is disposal tip — dispose of it after use.)	6. Dispensing the composite – Syringe Dispense the necessary amount of restorative material from the syringe onto the mixing pad by turning the handle slowly in a clockwise manner. A Universal Nano-hybrid Composite Immediately replace syringe cap. If not used immediately, the dispensed material should be protected from light. Place restorative material into the cavity using instrument contained. – Single dose capsule Insert capsule into dispenser and rotate to gain the proper angle of entrance into cavity. Extrude restorative directly into cavity, using a slow and steady pressure. 7. Placement Place and light cure restorative in increments in 2.5mm levels or less. For permitting extension of composite beyond cavity margins, overfill the cavity slightly. Avoid intense light in the working field.
	6) Curing Place a light projector as close as possible with the surface of the product filled and project the light for 20 seconds vertically. (Usage recommendation: D-Lux) (Increase the amount of projection when the projecting strength is below 400mW/cm2. If it is 400mW/cm2 or higher, reduce the amount of projection.)	8. Curing Expose each area of restoration surface to a visible light source (400mW/㎠). Hold the light guide tip as close to the restorative materials as possible during light exposure. The recommended exposure time and maximum increment thickness for each shade is shown below.
	7) Finishing up After restoring with the resin, remove the remaining resin with a flame-shaped finishing bur and complete the shape. Finish up the final grinding using a rubber polishing point and aluminium oxide polishing paste.	9. Finishing Immediately after curing contour restoration surfaces with fine finishing bur or stone. Carefully adjust occlusion by removing material with a fine polishing bur or stone.
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.) A1, A2, A3, A3.5, B1, B2, C1 20sec A2O, A3O, BL 30sec	20 seconds (If light curing unit output is below 400mW/cm2, as measured by a curing radiometer, more time may be needed.)

Human factor	Ready to use dispending system	Ready to use dispending system
Shelf life	3 years	2 years
Period of Use	Long term(> 30 days)	Long term(> 30 days)
Biocompatibility	Biocompatible, conforming to ISO 10993	Biocompatible, conforming to ISO 10993
Performance Standard conformance	Meet ISO 4049 standard	Meet ISO 4049 standard

7.2 differences

-Indication for Use

Subject Device	Primary Predicate Device	Discussion
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	DenFil™ is indicated for the following restorative applicantions; 1. Class I, II, V restorations of posterior teeth 2. Class III, IV, V restorations of anterior teeth 3. Cervical cavities or defects involving root surfaces	Intended use of both devices include restorations of restorations of anterior teeth / restorations posterior teeth/ defects involving root surfaces Indication for use of both devices is similar.

- Material composition

Subject Device DIAFIL	Predicate Device DENFIL	Function of ingredient
- Bis-GMA - TEGDMA - UDMA	- Bis-GMA - TEGDMA - UDMA - Bis-EMA	Base liquid resin
- Barium-alumino-silicate - Silica	- Barium-alumino-silicate - Silica	Filler
Camphorquinone	Camphorquinone	Photoinitiator
Pigments	Additives	Colorant

The raw material compositions of both devices are not identical but the main ingredient is similar and the role and functions are same. Also, the biocompatibility of raw material of subject device is confirmed by Biological safety study. Overall, the raw materials of both devices are similar.

- Shelf life

The shelf life of the subject device is 3years and the shelf life of the predicate device is 2 years.

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 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.

Performance test (Physical properties - ISO 4049:2009):

Item	Requirement	Result	Pass/Fail
Depth of cure	Opaque: shall be not less than 1 mm Non opaque: shall be not less than 1.5 mm	Opaque : 2.8 mm (min value) Non opaque :2.4 mm (min value)	Pass
Sensitivity of ambient light	Sample shall be no change in consistency	There was no change in consistency	Pass
Flexural strength	More than 80 Mpa	92.6 Mpa (min value)	Pass
Water sorption	shall be less than 40 μg/㎟	5.7 μg/㎟ (max value)	Pass
Solubility	shall be less than 7.5 μg/㎟	0.7 μg / ㎟ (max value)	Pass
Color	Color of samples shall be matched closely with the manufacturer's shade guide.	Color of samples was matched closely with the manufacturer's shade guide	Pass
Color stability	Shall be no color change	There was no color change	Pass
Radio-opacity	Sealer shall have radio-opacity equivalent to not less than 3 mm of aluminum	Not less than 3 mm of aluminum	Pass

Biocompatibility test:

Test	Standard (AAMI/ANSI/ISO)
Cytotoxicity	•10993-5 Biological Evaluation of Medical Devices – Part 5: Tests for in vitro Cytotoxicity
Oral mucosa irritation	•10993-10 Biological Evaluation of Medical Devices – Part 10: Tests for irritation and skin sensitization
Skin sensitization (LLNA)	•10993-10 Biological Evaluation of Medical Devices – Part 10: Tests for irritation and skin sensitization
Acute Systemic Toxicity	•10993-11 – Biological Evaluation of Medical Devices – Part 11: Tests for Systemic Toxicity
Genetoxicity: Bacterial Reverse Mutation	•10993-3 - Biological Evaluation of Medical Devices – Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
Genetoxicity: Micronucleus test	•10993-3 - Biological Evaluation of Medical Devices – Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity

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.