June 2, 2026

DiaDent Group International
Seung-Geun Lee
Regulatory Affairs Manager
16, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu,
Cheongju-si, Chungcheongbuk-do, 28161
REPUBLIC OF KOREA

Re: K261093
Trade/Device Name: DIAFIL
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: Class II
Product Code: EBF
Dated: April 2, 2026
Received: April 6, 2026

Dear Seung-Geun 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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S

Michael E. Adjodha, MChE, RAC, CQIA
Assistant Director
DHT1B: Division of Dental and
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OHT1: Office of Ophthalmic, Anesthesia,
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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)*
K261093

Device Name
DIAFIL

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
-. Core build-ups
-. Splinting

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

1. Application Information

Date Prepared	Apr 02, 2026
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	Seung-Geun Lee Regulatory Affairs Manager Phone: +82-43-266-2315 FAX: +82-43-235-2315 Email: diadent33@diadent.co.kr

2. Device Information

Device Type	Material, Tooth Shade, Resin
Regulation Description	Tooth shade resin material
Review Panel	Dental
Regulation Number	21 CFR 872.3690
Product Code	EBF
Device Class	II
Device Name	DIAFIL

3. Primary Predicate Device

510(k) Number	K192510
Applicant	DiaDent Group International
Device Name	DIAFIL & DIAFIL Capsule
Regulation Number	21 CFR 872.3690
Product Code	EBF
Device Class	II

4. Device Description

DIAFIL is a composite dental resin for aesthetic restoration corresponding to Type 1, Class 2 and Group 1 of ISO 4049:2019 and is used in direct restoration of cavity by being polymerized in oral cavity.

No.	Model Name	Composition
1	DIAFIL A1 Refill Package	DIAFIL A1 4g Syringe 1ea
2	DIAFIL A2 Refill Package	DIAFIL A2 4g Syringe 1ea
3	DIAFIL A3 Refill Package	DIAFIL A3 4g Syringe 1ea

4	DIAFIL A3.5 Refill Package	DIAFIL A3.5 4g Syringe 1ea
5	DIAFIL A4 Refill Package	DIAFIL A4 4g Syringe 1ea
6	DIAFIL B1 Refill Package	DIAFIL B1 4g Syringe 1ea
7	DIAFIL B2 Refill Package	DIAFIL B2 4g Syringe 1ea
8	DIAFIL B3 Refill Package	DIAFIL B3 4g Syringe 1ea
9	DIAFIL B4 Refill Package	DIAFIL B4 4g Syringe 1ea
10	DIAFIL C1 Refill Package	DIAFIL C1 4g Syringe 1ea
11	DIAFIL C2 Refill Package	DIAFIL C2 4g Syringe 1ea
12	DIAFIL C3 Refill Package	DIAFIL C3 4g Syringe 1ea
13	DIAFIL C4 Refill Package	DIAFIL C4 4g Syringe 1ea
14	DIAFIL D1 Refill Package	DIAFIL D1 4g Syringe 1ea
15	DIAFIL D2 Refill Package	DIAFIL D2 4g Syringe 1ea
16	DIAFIL D3 Refill Package	DIAFIL D3 4g Syringe 1ea
17	DIAFIL D4 Refill Package	DIAFIL D4 4g Syringe 1ea
18	DIAFIL CL Refill Package	DIAFIL CL 4g Syringe 1ea
19	DIAFIL A1_Intro Kit	DIAFIL A1 1g Syringe 1ea
20	DIAFIL A2_Intro Kit	DIAFIL A2 1g Syringe 1ea
21	DIAFIL A3_Intro Kit	DIAFIL A3 1g Syringe 1ea
22	DIAFIL A3.5_Intro Kit	DIAFIL A3.5 1g Syringe 1ea
23	DIAFIL A4_Intro Kit	DIAFIL A4 1g Syringe 1ea
24	DIAFIL B1_Intro Kit	DIAFIL B1 1g Syringe 1ea
25	DIAFIL B2_Intro Kit	DIAFIL B2 1g Syringe 1ea
26	DIAFIL B3_Intro Kit	DIAFIL B3 1g Syringe 1ea
27	DIAFIL B4_Intro Kit	DIAFIL B4 1g Syringe 1ea
28	DIAFIL C1_Intro Kit	DIAFIL C1 1g Syringe 1ea
29	DIAFIL C2_Intro Kit	DIAFIL C2 1g Syringe 1ea

30	DIAFIL C3_Intro Kit	DIAFIL C3 1g Syringe 1ea
31	DIAFIL C4_Intro Kit	DIAFIL C4 1g Syringe 1ea
32	DIAFIL D1_Intro Kit	DIAFIL D1 1g Syringe 1ea
33	DIAFIL D2_Intro Kit	DIAFIL D2 1g Syringe 1ea
34	DIAFIL D3_Intro Kit	DIAFIL D3 1g Syringe 1ea
35	DIAFIL D4_Intro Kit	DIAFIL D4 1g Syringe 1ea
36	DIAFIL CL_Intro Kit	DIAFIL CL 1g Syringe 1ea
37	DIAFIL Capsule Type A1	DIAFIL A1 0.25g Capsule Type 20ea
38	DIAFIL Capsule Type A2	DIAFIL A2 0.25g Capsule Type 20ea
39	DIAFIL Capsule Type A3	DIAFIL A3 0.25g Capsule Type 20ea
40	DIAFIL Capsule Type A3.5	DIAFIL A3.5 0.25g Capsule Type 20ea
41	DIAFIL Capsule Type A4	DIAFIL A4 0.25g Capsule Type 20ea
42	DIAFIL Capsule Type B1	DIAFIL B1 0.25g Capsule Type 20ea
43	DIAFIL Capsule Type B2	DIAFIL B2 0.25g Capsule Type 20ea
44	DIAFIL Capsule Type B3	DIAFIL B3 0.25g Capsule Type 20ea
45	DIAFIL Capsule Type B4	DIAFIL B4 0.25g Capsule Type 20ea
46	DIAFIL Capsule Type C1	DIAFIL C1 0.25g Capsule Type 20ea
47	DIAFIL Capsule Type C2	DIAFIL C2 0.25g Capsule Type 20ea
48	DIAFIL Capsule Type C3	DIAFIL C3 0.25g Capsule Type 20ea
49	DIAFIL Capsule Type C4	DIAFIL C4 0.25g Capsule Type 20ea
50	DIAFIL Capsule Type D1	DIAFIL D1 0.25g Capsule Type 20ea
51	DIAFIL Capsule Type D2	DIAFIL D2 0.25g Capsule Type 20ea
52	DIAFIL Capsule Type D3	DIAFIL D3 0.25g Capsule Type 20ea
53	DIAFIL Capsule Type D4	DIAFIL D4 0.25g Capsule Type 20ea
54	DIAFIL Capsule Type CL	DIAFIL CL 0.25g Capsule Type 20ea

5. 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
-. Core build-ups
-. Splinting

6. Technological Characteristics

The subject device, DIAFIL has similar characteristics to the primary predicate device, DIAFIL & DIAFIL Capsule.

[Comparison table]

	Subject Device	Predicate Device	Discuss
510(k) Number	-	K192510	-
Product Code	EBF	EBF	Equivalent
Device Class	II	II	Equivalent
Manufacturer	DiaDent Group International	DiaDent Group International	-
Device Name	DIAFIL	DIAFIL & DIAFIL Capsule	-
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 -. Core build-ups -. Splinting	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	Equivalent
Raw Materials	-Urethane dimethacrylate -Bisphenol A glycidyl methacrylate Triethylene glycol dimethacrylate -Trimethylolpropane trimethacrylate - BYK-405 - Barium glass powder - Barium glass powder - SiO2 - Camphorquinone -Ethyl-4-(Dimethylamino)benzoate(EDB) - Dibutyl hydroxy toluene (BHT)	- Bisphenol A epoxymethacrylate/Triethyleneglycol dimethacrylate - Triethyleneglycol dimethacrylate - Urethane dimethacrylate - Ethoxylated Bisphenol A dimethacrylate - Glass Composition - Pyrogenic colloidal silica treated with 3-methacryloxy propyl trimethoxy silane - D,L-Camphorquinone - Ethyl 4-dimethylaminobenzoate	* See the below table.

	- 2-hydroxy-4-(octyloxy)benzophenone	-2-Hydroxy-4-n-octoxybenzophenone -2,6-di-tert-butyl-p-cresol -4-Methoxyphenol	
Principle of operation	light-cured restorative composite resin and accessories for use in both posterior and anterior restoration.	light-cured restorative hybrid composite resin and accessories for use in both posterior and anterior restoration.	Equivalent
Performance Standard Conformance	Conformed ISO 4049	Conformed ISO 4049	Equivalent
Physical and Mechanical properties	-. Water sorption -. Solubility -. Depth of cure -. Flexural strength -. Radiopacity	-. Water sorption -. Solubility -. Depth of cure -. Flexural strength -. Radiopacity	Equivalent
Biocompatibility	Biocompatible	Biocompatible	Equivalent
Use	Prescription / Hospital	Prescription / Hospital	Equivalent
Period of use	Permanent	Permanent	Equivalent
Sterility	Non-sterile	Non-sterile	Equivalent
Shelf-life	3 years	3 years	Equivalent

* Difference table

Subject Device	Predicate Device	Discussion
-Urethane dimethacrylate -Bisphenol A glycidyl methacrylate Triethylene glycol dimethacrylate -Trimethylolpropane trimethacrylate - BYK-405 - Barium glass powder - Barium glass powder - SiO2 - Camphorquinone -Ethyl-4-(Dimethylamino)benzoate(EDB) - Dibutyl hydroxy toluene (BHT) - 2-hydroxy-4-(octyloxy)benzophenone	- Bisphenol A epoxymethacrylate/Triethyleneglycol dimethacrylate - Triethyleneglycol dimethacrylate - Urethane dimethacrylate - Ethoxylated Bisphenol A dimethacrylate - Glass Composition - Pyrogenic colloidal silica treated with 3-methacryloxy propyl trimethoxy silane - D,L-Camphorquinone - Ethyl 4-dimethylaminobenzoate -2-Hydroxy-4-n-octoxybenzophenone -2,6-di-tert-butyl-p-cresol -4-Methoxyphenol	The main raw material, Bis-GMA (Bisphenol A-Glycidyl Methacrylate), used in the subject device is the same as that used in the predicate device. The biocompatibility test results demonstrate that this material does not raise any safety or effectiveness concerns.

7. Non-Clinical Performance Data
The performance and biological tests were conducted on the subject device; DIAFIL according to the following standards.

ISO 4049:2019, Dentistry — Polymer-based restorative materials
ISO 7405:2018, Dentistry — Evaluation of biocompatibility of medical devices used in dentistry
ISO 10993-1:2018, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
ISO 10993-3:2014, Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
ISO 10993-5:2009, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
ISO 10993-10:2010, Biological evaluation of medical devices - Part 10: Tests for skin sensitization
ISO 10993-11:2017, Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
ISO 10993-23:2021, Biological evaluation of medical devices - Part 23: Tests for irritation

The test results corresponded the requirements of standards. Therefore, the subject device is substantially equivalent in safety and effectiveness to the predicate device.

8. Clinical Performance Data
No clinical data was collected or provided to support substantial equivalence between the subject and predicate device.

9. Conclusions
Based on the above information and all data provided in this submission, the subject device is substantially equivalent to the legally marketed device identified in this submission.