May 19, 2026

DiaDent Group International
Seung-Geun Lee
Regulatory Affairs Manager
16, Osongsaengmyeong 4-Ro, Osong-Eup, Heungdeok-Gu,
Cheongju-Si, 28186 KOR

Re: K261071
Trade/Device Name: DIAFIL Bulk FLOW (Economic Package);DIAFIL Bulk FLOW (Refill Package);DIAFIL Bulk FLOW (0.5g)
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: Class II
Product Code: EBF
Dated: March 31, 2026
Received: April 2, 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,

FDA Bobak Shirmohammadi -S

For Michael E. Adjodha, M.ChE., RAC, CQIA
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)*
K261071

Device Name
DIAFIL Bulk FLOW (Economic Package);
DIAFIL Bulk FLOW (Refill Package);
DIAFIL Bulk FLOW (0.5g)

Indications for Use *(Describe)*
- Base under Class I, II direct restorations
- Liner under direct restorative materials
- Repair of composite/ceramic veneers
- Restorations of small posterior cavities
- Undercut block-out
- Pit & Fissure sealant

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	Mar 31, 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-guen 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 Bulk FLOW

3. Primary Predicate Device

510(k) Number	K173275
Applicant	Tokuyama Dental
Device Name	OMNICHROMA
Regulation Number	21 CFR 872.3690
Product Code	EBF
Device Class	II

4. Device Description

DIAFIL Bulk FLOW is a composite dental resin for aesthetic restoration corresponding to Type 1, Class 2 and Group 1 of ISO4049 and is used in direct restoration of cavity by being polymerized in oral cavity.

No.	Model Name	Composition
1	DIAFIL Bulk FLOW Economic Package	2g syringe x 5ea, Disposable Tip 18G x 25ea
2	DIAFIL Bulk FLOW Refill Package	2g syringe x 1ea, Disposable Tip 18G x 5ea
3	DIAFIL Bulk FLOW 0.5g	0.5g syringe x 1ea, Disposable Tip 18G x 1ea

5. Indications for Use

- Base under Class I, II direct restorations

- Liner under direct restorative materials
- Repair of composite/ceramic veneers
- Restorations of small posterior cavities
- Undercut block-out
- Pit & Fissure sealant

6. Technological Characteristics

The subject device, DIAFIL Bulk FLOW has similar characteristics to the primary predicate device, OMNICHROMA.

[Comparison table]

	Subject Device	Predicate Device	Discuss
510(k) Number	-	K173275	-
Product Code	EBF	EBF	Equivalent
Device Class	II	II	Equivalent
Manufacturer	DiaDent Group International	Tokuyama Dental Corporation	-
Device Name	DIAFIL Bulk FLOW	OMNICHROMA	-
Indications for Use	- Base under Class I, II direct restorations - Liner under direct restorative materials - Repair of composite/ceramic veneers - Restorations of small posterior cavities - Undercut block-out - Pit & Fissure sealant	- Direct anterior and posterior restorations - Direct bonded composite veneer - Diastema closure - Repair of porcelain/composite	* See the below table.
Raw Materials	- Bisphenol A poxymethacrylate /triethyleneglycol dimethacrylate - Triethyleneglycol dimethacrylate - Diurthane dimethacrylate - Long-chain Urethane dimethacrylate - Ethoxylated Bisphenol A dimethacrylate - Barium glass - Fumed silica - (+/-)-Camphorquinone - Ethyl 4-dimethylaminobenzoate - 2-Hydroxy-4-n-octoxybenzophenone - 2,6-di-tert-butyl-p-cresol	- 1, 6-bis(methacryl-ethyloxy carbonylamino)trimethylhexane(UDMA) - Triethylene glycol dimethacrylate(TEGDMA)	* See the below table.

	- 4-Methoxyphenol - Iron oxide red - Titanium dioxide		
Principle of operation	The product is classified as a Type 1, Class 2, Group 1 material according to ISO 4049. It is a light-curing, aesthetic restorative composite resin intended for both anterior and posterior applications. The material consists of a paste containing unpolymerized dimethacrylate monomers, inorganic fillers, and a photoinitiator system. It is used for restorations requiring aesthetics due to dental caries or structural damage. After placement of the uncured material into the cavity, it is polymerized using a dental visible light-curing unit, resulting in a hardened and durable restoration.	Tooth shade resin material that is cured by photo polymerization. (Lightcure)	Equivalent
Performance Standard Conformance	Conformed ISO 4049	Conformed ISO 4049	Equivalent
Physical and Mechanical properties	- Water sorption - Solubility - Depth of Cure - Flexural strength - Colour - Colour stability - Radiopacity - Sensitivity to ambient light	- Sensitivity to ambient light - Depth of cure - Flexural strength - Water sorption - Solubility - Color stability - Radio-opacity	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
- Indications for Use

Subject Device	Predicate Device	Discussion
- Base under Class I, II direct restorations - Liner under direct restorative materials - Repair of composite/ceramic veneers - Restorations of small posterior cavities - Undercut block-out - Pit & Fissure sealant	- Direct anterior and posterior restorations - Direct bonded composite veneer - Diastema closure - Repair of porcelain/composite	The indications of the subject device is similar to the indications of the predicate device, and it does not contain new indications.

- Raw materials

Subject Device	Predicate Device	Discussion
- Bisphenol A epoxymethacrylate /triethyleneglycol dimethacrylate - Triethylene glycol dimethacrylate - Diurthane dimethacrylate - Urethane dimethacrylate - Ethoxylated Bisphenol A dimethacrylate - Barium glass - Fumed silica - (+/-)-Camphorquinone - Ethyl 4-dimethylaminobenzoate - 2-Hydroxy-4-n-octoxybenzophenone - 2,6-di-tert-butyl-p-cresol - 4-Methoxyphenol - Iron oxide red - Titanium dioxide	- 1, 6-bis(methacryl-ethyloxy carbonylamino)trimethylhexane (UDMA) - Triethylene glycol dimethacrylate(TEGDMA)	Triethylene glycol dimethacrylate, is contained in both subject device and predicate device. Through the biocompatibility test results, the difference does not raise any issue of safety and effectiveness.

7. Non-Clinical Performance Data

The performance and biological tests were conducted on the subject device; DIAFIL Bulk FLOW 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 10993-10:2021, 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 10993-17:2023, Biological evaluation of medical devices—Part 17: Toxicological risk assessment of medical device constituents

ISO 10993-18:2020/Amd 1:2022, Biological evaluation of medical devices — Part 18: Chemical characterization of medical device materials within a risk management process—Amendment 1: Determination of the uncertainty factor
ISO 10993-23:2021, Biological evaluation of medical devices—Part 23: Tests for irritation

The test results corresponded to 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.