July 9, 2026

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

Re: K261166
Trade/Device Name: DIA-CEM
Regulation Number: 21 CFR 872.3275
Regulation Name: Dental Cement
Regulatory Class: Class II
Product Code: EMA
Dated: April 9, 2026
Received: April 9, 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,

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K261166

Device Name
DIA-CEM

Indications for Use *(Describe)*
- Resin crowns, bridges, inlays and onlays
- Glass ceramic, porcelain crowns, inlays and onlays (includes alumina and zirconia)
- Metal crowns, bridges, inlays and onlays (includes porcelain fused to metal and composite to metal)
- Metal (prefabricated or cast) and fiber posts

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) substantial equivalence information is submitted in accordance with the requirements of 21 CFR 807.92.

1. Application Information

Date Prepared	Apr 09, 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	Cement, Dental
Regulation Description	Dental cement
Review Panel	Dental
Regulation Number	21 CFR 872.3275
Product Code	EMA
Device Class	II
Device Trade Name	DIA-CEM

3. Predicate Device

-	Primary Predicate Device	Predicate Device
510(k) Number	K082449	K171449
Applicant	BICO, Inc.	META BIOMED CO., LTD.
Device Name	BISCEM	Metacem
Regulation Number	21 CFR 872.3275	21 CFR 872.3275
Product Code	EMA	EMA
Device Class	II	II

4. Device Description

DIA-CEM is a radiopaque resin cement that can be used in self-cure or light-cure mode.
It corresponds to type 2 class 3 of ISO 4049 and contains more than 60% of inorganic filler.
DIA-CEM shows high bonding strength on various materials, yet excess material can be easily removed. 3 different shades are available: TR, A2, and A3O.

No.	Model Name	Composition
1	DIA-CEM TR 9g	DIA-CEM TR 9g Syringe 1ea + Mixing tip 3ea + Root Canal tip 3ea + Eco tip & Cap 1ea
2	DIA-CEM A2 9g	DIA-CEM A2 9g Syringe 1ea + Mixing tip 3ea + Root Canal tip 3ea + Eco tip & Cap 1ea

3	DIA-CEM A3O 9g	DIA-CEM A3O 9g Syringe 1ea + Mixing tip 3ea + Root Canal tip 3ea + Eco tip & Cap 1ea
4	DIA-CEM TR 3g	DIA-CEM TR 3g Syringe 1ea + Mixing tip 1ea + Root Canal tip 1ea + Eco tip 1ea
5	DIA-CEM A2 3g	DIA-CEM A2 3g Syringe 1ea + Mixing tip 1ea + Root Canal tip 1ea + Eco tip 1ea
6	DIA-CEM A3O 3g	DIA-CEM A3O 3g Syringe 1ea + Mixing tip 1ea + Root Canal tip 1ea + Eco tip 1ea

5. Indications for Use
-Resin crowns, bridges, inlays and onlays
-Glass ceramic, porcelain crowns, inlays and onlays (includes alumina and zirconia)
-Metal crowns, bridges, inlays and onlays (includes porcelain fused to metal and composite to metal)
-Metal (prefabricated or cast) and fiber posts

6. Technological Characteristics
The subject device, DIA-CEM has similar characteristics to the primary predicate device, BISCEM and MetaCem.

[Comparison table]

	Subject Device	Predicate Device	Predicate Device	Discuss
510(k) Number	K261166	K082449	K171449	-
Product Code	EMA	EMA	EMA	Equivalent
Device Class	II	II	II	Equivalent
Manufacturer	DiaDent Group International	BISCO, Inc.	Meta Biomed Co., Ltd	-
Device Name	DIA-CEM	BISCEM	MetaCem	-
Indication for Use	- Resin crowns, bridges, inlays and onlays - Glass ceramic, porcelain crowns, inlays and onlays(includes alumina and zirconia) - Metal crowns, bridges, inlays and onlays(includes porcelain fused to metal and composite to metal) - Metal(prefabricated or cast) and fiber posts	- Luting metal crowns, bridges, inlay, and onlays including porcelain-fused-to-metal and composite-to-metal varieties - Luting resin crowns, bridges, inlays, onlays, and veneers; - Luting metal or non-metal/fiber posts; - Luting orthodontic appliances; - Luting porcelain inlays, onlays, crowns, and veneers(includes	Adhesive cementation of: - Crown & Bridges (Ceramic, Composite, Porcelain, Metal) - Inlay / Onlay cementation - Bonding for porcelain veneers - Endodontic posts cementation - Core build up	Equivalent

		alumina and zirconia)		
Intended Purpose	Resin-based adhesive material used to bond brackets, restorations, etc. to the tooth surface	The modified formula is a dual-cure radiopaque dental cement designed to be used as a luting cement.	Metacem is intended for use in the cementing or fixation of restorations and appliances such as inlays, onlays, veneers, crowns, bridges and posts classed by Type 2, Class 3 according to ISO 4049.	Equivalent
Raw Materials	- Urethane dimethacrylate - bisphenol A glycidyl methacrylate / Triethyleneglycol dimethacrylate - 10-Methacryloxydecyl Dihydrogen Phosphate - 2-Hydroxy ethyl methacrylate - Barium glass - Silica - (±)-Camphorquinone - Ethyl 4-dimethylaminobenzoate - 1-(Pyridin-2-yl)thiourea - 2,6-di-tert-butyl-p-cresol - 2-Hydroxy-4-n-octoxybenzophenone - Copper(II) Acetate monohydrate - Cumyl hydroperoxide - 2,6-di-tert-butyl-ρ-cresol - pigments	-Bisphenol A Diglycidylmethacrylate -Amorphous Silica -Initiator -Bis[2-(Methacryloxy)ethyl]Phosphate -Monomer (Bis(Glyceryl 1, 3 Dimethacrylate) Phosphate -Aluminum Oxide	- Bis-GMA[Bisphenol A Glycerolate(glycerol/phenol) dimethacrylate] - TEGDMA [Tri(ethylene glycol)dimethacrylate] - Camphorquinone - DEPT [2,2'-(P-Tolyimino)diethanol]	* See the below table.
Device Description	DIA-CEM is a radiopaque resin cement that can be	BisCem is dual-cured self etching and self adhesive	Metacem is a high strength, permanent visible	Equivalent

	used in self-cure or light cure mode. It corresponds to type 2 class 3 of ISO 4049 and contains more than 60% of inorganic filler. DIA-CEM shows high bonding strength on various materials, yet excess material can be easily removed. 3 different shades are available: TR, A2, and A3O.	resin cement. It is a self-adhesive cement since it bonds to composite, metal, silanated porcelain and tooth structure without applying any adhesive. No etching step is required to bond to dentin or enamel. With its dual syringe system. BisCem can be self cured by simply mixing paste A and paste B or cured by light after mixing paste A and paste B. Using a mixing tip, the cement could be dispensed to the working area directly. It is intended for use as a luting cement. Due to the unique chemistry of BisCem, refrigeration is necessary when not in use. Allow refrigerated BisCem to reach room temperature before use.	light cured(VLC), dual cured or self-cured resin cement for use with dentin/enamel adhesive prime and bone systems, to adhesively bond and lute indirect restorations to tooth structure. Metacem consists of a methacrylate base paste and catalyst paste which in use are instantly mixed from a dual syringe of form a dual-cured cement. This mixed version of the cement will self-cure or can be light cured, or both. The dual cure is effective for dark shade, thick or opaque cementation.	
Performance Standard Conformance	Conformed ISO 4049 and ISO 29022	Conformed ISO 4049	Conformed ISO 4049	Equivalent
Physical and Mechanical properties	Film thickness : ≤ 50μm	-	- Film thickness : 26.4μm	Similar
	Flexural strength : ≥ 50MPa	-	Flexural strength : 120.5MPa	
	Water sorption : ≤ $40\mu g/mm^3$	-	Water sorption : $14.0\mu g/mm^3$	
	Solubility : ≤ $7.5\mu g/mm^3$	-	Solubility : $0.5\mu g/mm^3$	
	Radiopacity	Radiopacity	Radiopacity	
	Working time : ≥ 60sec	-	Working time : homogeneous	

	Setting time : ≤ 10min	-	Setting time A1: 3min 14sec A3: 3min 04sec B2: 3min 57sec OP: 3min 34sec TL: 2min 28sec	
	Color/Color stability : Consistency	-	Color/Color stability : Consistency	
Biocompatibility	Biocompatible	Biocompatible	Biocompatible	Equivalent
Use	Prescription / Hospital	Prescription / Hospital	Prescription / Hospital	Equivalent
Sterility	Non-sterile	Non-sterile	Non-sterile	Equivalent
Shelf-life	2 years	2 years	2 years	Equivalent

* Difference table

Subject Device	Predicate Device	Predicate Device	Discussion
- Urethane dimethacrylate - bisphenol A glycidyl methacrylate / Triethyleneglycol dimethacrylate - 10-Methacryloxydecyl Dihydrogen Phosphate - 2-Hydroxy ethyl methacrylate - Barium glass - Silica - (±)-Camphorquinone - Ethyl 4-dimethylaminobenzoate - 1-(Pyridin-2-yl)thiourea - 2,6-di-tert-butyl-p-cresol - 2-Hydroxy-4-n-octoxybenzophenone - Copper(II) Acetate monohydrate - Cumyl hydroperoxide	-Bisphenol A Diglycidylmethacrylate -Amorphous Silica -Initiator -Bis[2-(Methacryloxy)ethyl]Phosphate -Monomer (Bis(Glyceryl 1, 3 Dimethacrylate) Phosphate -Aluminum Oxide	- Bis-GMA[Bisphenol A Glycerolate(glycerol/phenol) dimethacrylate] - TEGDMA [Tri(ethylene glycol)dimethacrylate] - Camphorquinone - DEPT [2,2'-(P-Tolyimino)diethanol]	The subject device and the predicate devices all utilize the same primary resin matrix derived from Bisphenol A. Since the core structure of all three devices is based on this identical Bisphenol-type monomer, the fundamental chemical performance and safety profile are considered substantially equivalent. Although there are minor variations in the specific monomeric composition and additive packages (such as fillers or initiators), comprehensive biocompatibility testing has demonstrated that these differences do not adversely affect the safety or clinical effectiveness of the device.

- 2,6-di-tert-butyl-ρ-cresol - pigments			

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

ISO 4049:2019, Dentistry — Polymer-based restorative materials
ISO 29022:2013, Dentistry — Adhesion — Notched-edge shear bond strength test
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 10993-23:2021, 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.