July 28, 2023

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

Re: K231552
Trade/Device Name: Dia-Cem
Regulation Number: 21 CFR 872.3275
Regulation Name: Dental Cement
Regulatory Class: Class II
Product Code: EMA
Dated: May 16, 2023
Received: May 30, 2023

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,

Michael E. Adjodha -S

Michael E. Adjodha, M.ChE.
Assistant Director
DHT1B: Division of Dental and
ENT Devices
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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)*

K231552

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.

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K231552

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	May 10, 2023
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

Common Name	Dental Resin Cement
Trade Name	Dia-Cem
Classification Name	Cement, Dental (21 CFR 872.3275)
Product Code	EMA
Device Class	II

3. Primary Predicate Device

510(k) Number	K082449
Applicant	BISCO, Inc.
Device Name	BisCem
Regulation Number	21 CFR 872.3275
Product Code	EMA
Device Class	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 and 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 + Automixing tip 3ea + Root canal tip 3ea + Eco tip 1ea
		Dia-Cem TR 9g syringe 1ea + Automixing tip 5ea + Root canal tip 5ea + Eco tip 1ea
		Dia-Cem TR 9g syringe 1ea + Automixing tip 10ea + Root canal tip 10ea + Eco tip 1ea
		Dia-Cem TR 9g syringe 1ea + Automixing tip 10ea + Eco tip 1ea
		Dia-Cem TR 9g syringe 1ea + Automixing tip 5ea + Eco tip 1ea

		Dia-Cem TR 9g syringe 1ea + Automixing tip 3ea + Eco tip 1ea
2	Dia-Cem A2 9g	Dia-Cem A2 9g syringe 1ea + Automixing tip 3ea + Root canal tip 3ea + Eco tip 1ea
		Dia-Cem A2 9g syringe 1ea + Automixing tip 5ea + Root canal tip 5ea + Eco tip 1ea
		Dia-Cem A2 9g syringe 1ea + Automixing tip 10ea + Root canal tip 10ea + Eco tip 1ea
		Dia-Cem A2 9g syringe 1ea + Automixing tip 10ea + Eco tip 1ea
		Dia-Cem A2 9g syringe 1ea + Automixing tip 5ea + Eco tip 1ea
		Dia-Cem A2 9g syringe 1ea + Automixing tip 3ea + Eco tip 1ea
3	Dia-Cem A3O 9g	Dia-Cem A3O 9g syringe 1ea + Automixing tip 3ea + Root canal tip 3ea + Eco tip 1ea
		Dia-Cem A3O 9g syringe 1ea + Automixingtip 5ea + Root canal tip 5ea + Eco tip 1ea
		Dia-Cem A3O 9g syringe 1ea + Automixing tip 10ea + Root canal tip 10ea + Eco tip 1ea
		Dia-Cem A3O 9g syringe 1ea + Automixing tip 10ea + Eco tip 1ea
		Dia-Cem A3O 9g syringe 1ea + Automixing tip 5ea + Eco tip 1ea
		Dia-Cem A3O 9g syringe 1ea + Automixing tip 3ea + Eco tip 1ea
4	Dia-Cem TR 3g	Dia-Cem TR 3g + Eco tip 1ea
5	Dia-Cem A2 3g	Dia-Cem A2 3g + Eco tip 1ea
6	Dia-Cem A3O 3g	Dia-Cem A3O 3g + 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.

[Comparison table]

	Subject Device	Predicate Device	Discuss
510(k) Number	-	K082449	-
Product Code	EMA	EMA	Equivalent
Device Class	II	II	Equivalent
Manufacturer	DiaDent Group International	Bisco, Inc.	-
Device Name	Dia-Cem	BisCem	-
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	- Luting resin crowns, bridges, inlays, onlays and veneers - Luting porcelain inlays, onlays, crowns, and veneers (includes alumina and zirconia)	Equivalent

	(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 variteties - Luting metal or non-metal/fiber posts - Luting orthodontic appliances	
Raw Materials	- Ethoxylated bisphenol A dimethacrylate - 10-Methacryloxy decyl dihydrogen phosphate - 2-Hydroxyethyl Methacrylate - Barium glass - (+/-)-Camphorquinone - 2, 6-di-tert-butyl-p-cresol - Pigments	- Bisphenol A diglycidylmethacrylate - Bis[2-(Methacryloyloxy) ethyl]Phosphate - 2-Hydroxyethyl Methacrylate - Bis(Glyceryl 1,3 Dimethacrylate) Phosphate	* See the below table.
Principle of operation	Dia-Cem is a radiopaque resin cement that can be used in self-cure or light-cure mode. When the light is irradiated, the polymerization is generated from the photoinitiator. Also, the polymerization is generated from the reaction which takes place by the peroxide initiator.	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.	Equivalent
Performance Standard Conformance	Conformed ISO 4049 and ISO 29022	Conformed ISO 4049	Equivalent
Physical and Mechanical properties •Working time	A homogeneous and thin film should be formed at 60 sec after the complete of mixing.	A homogeneous and thin film should be formed at 60 sec after the complete of mixing.	Equivalent
•Flexural strength	More than 50 MPa	More than 50 MPa	Equivalent
•Film thickness	No greater than 50 ㎛	No greater than 50 ㎛	Equivalent
•Shear bond strength	Equal or greater than 4 MPa	Equal or greater than 4 MPa	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	2 years	2 years	Equivalent

* Difference table

Subject Device	Predicate Device	Discussion
- Ethoxylated bisphenol A dimethacrylate - 10-Methacryloxy decyl dihydrogen phosphate - 2-Hydroxyethyl Methacrylate - Barium glass - (+/-)-Camphorquinone - 2, 6-di-tert-butyl-p-cresol - Pigments	- Bisphenol A diglycidylmethacrylate - Bis[2-(Methacryloyloxy) ethyl]Phosphate - 2-Hydroxyethyl Methacrylate - Bis(Glyceryl 1,3 Dimethacrylate) Phosphate - Amorphous Silica - Aluminum oxide	The main raw material, Ethoxylated bisphenol A dimethacrylate of the subject device is similar to Bisphenol A diglycidylmethacrylate of the predicate device. Also, 2-hydroxyethyl methacrylate 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; 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, Evaluation and testing within a risk management process
ISO 10993-3:2014, Tests for genotoxicity, carcinogenicity and reproductive toxicity
ISO 10993-5:2009, Tests for in vitro cytotoxicity
ISO 10993-10:2010, Tests for irritation and skin sensitization
ISO 10993-11:2017, Tests for systemic toxicity

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.