August 13, 2026

Mediclus Co., Ltd.
Ku Da Hyeon
RA Associate
1210, 134, Gongdan-Ro, Heungdeok-Gu
Cheongju-Si, 28576
Republic Of Korea

Re: K254201
Trade/Device Name: Any-Cem
Regulation Number: 21 CFR 872.3275
Regulation Name: Dental Cement
Regulatory Class: Class II
Product Code: EMA
Dated: July 21, 2026
Received: July 21, 2026

Dear Ku Da Hyeon:

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K254201

Please provide the device trade name(s).

Any-Cem

Please provide your Indications for Use below.

- Metal crowns, bridges, inlays and onlays
- Resin crowns, bridges, inlays and onlays
- All ceramic

Please select the types of uses (select one or both, as applicable).

- [x] Prescription Use (21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

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510(k) Summary

This summary of 510(K) information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: August 12, 2026

1. Submitter/Contact Person

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3. Device

- Trade Name: Any-Cem
- Common Name: Dental Resin-based Cement
- Classification Name: Dental Cement
- Product Code: EMA
- Classification regulation: 21 CFR 872.3275

4. Comparison Devices

- Primary Predicate Device: Dia-Cem by DiaDent Group International (K231552)
- Reference Device: MAXCEM 2 by Kerr Corporation (K073209)
  - K073209 was included as a reference device to provide additional support for the performance characteristics of the subject device. Comparative testing of water sorption and solubility was conducted between the subject device and Maxcem, which

was cleared under K073209. The comparable results support the substantial equivalence of the subject device with respect to these performance characteristics.

5. Description:

Any-Cem is a dental resin-based cement intended for dental restorations. It is designed for use in restorative dental procedures in accordance with its intended use. It is available in three shades: Universal, White and TL. Any-Cem is a radiopaque resin cement that can be used in self-cure or light-cure mode. It shows high bonding strength on various materials, yet excess material can be easily removed.

6. Indication for use:

- Metal crowns, bridges, inlays and onlays
- Resin crowns, bridges, inlays and onlays
- All ceramic

7. Basis for Substantial Equivalence

7.1. Comparison Chart

	Subject Device	Predicate Device	Reference Device	Equivalence evaluation
Manufacturer	MEDICLUS Co., Ltd.	DiaDent Group International	Kerr Corporation	-
Product Name	Any-Cem	Dia-Cem	Maxcem 2	-
510k#	-	K231552	K073209	-
Product Code	EMA	EMA	EMA	-
Material	- Bisphenol A glycerolate dimethacrylate - 2-Hydroxyethyl methacrylate - Brium glass - Camphorquinone - 2,6-di-tert-butyl-pcresol - Pigments	- Ethoxylated bisphenol A dimethacrylate - 10-Methacryloxy decyl dihydrogen phosphate - 2-Hydroxyethyl Methacrylate - Barium glass - (+/-)-Camphorquinone - 2, 6-di-tert-butyl-pcresol - Pigments	- 2-hydroxyethyl methacrylate - 2-hydroxy-1,3-propanediyl bismethacrylate - 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12- diazahexadecane-1,16-diyl bismethacrylate - Ytterbium trifluorid	Similar
Curing type	Dual-cured (Self-curing, Ligh-curing)	Dual-cured (Self-curing, Ligh-curing)	Dual-cured (Self-curing, Ligh-curing)	Same
Indications for Use Statement	- Metal crowns, bridges, inlays and onlays - Resin crowns, bridges, inlays and onlays - All ceramic	- 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 compositeto-metal) -Metal (prefabricated or cast) and	- Cementation of all indirect restorations including ceramic, resin and metal-based inlays, onlays, crowns, bridges, posts, and veneers. - Cementation of crown restoration to implants.	Same

			fiber posts		
Intended User		Licensed Dentist or Dental Professional	Licensed Dentist or Dental Professional	Licensed Dentist or Dental Professional	Same
Technological Characteristics	**Standard**	ISO 4049 and ISO 29022	ISO 4049 and ISO 29022	ISO 4049 and ISO 29022	Similar
	Film thickness	≤ 50 ㎛	≤ 50 ㎛	-	
	Working time	≥ 60 sec	3 min	-	
	Setting time	≤ 10 min	5 min	-	
	Flexural strength	≥ 50 MPa	≥ 50 MPa	-	
	Bond strength	≥ 5 MPa	≥ 4 MPa	-	
	Water sorption	≤ 40 ㎍/㎣	-	Met specification	Similar
	Solubility	≤ 7.5 ㎍/㎣	-	≤ 7.5 ㎍/㎣	
Biocompatibility		Biocompatible	Biocompatible	Biocompatible	Same
Delivery method		• Delivery System: Syringe • Weight: 6g • Automix tips, Eco-tips	• Delivery System: Syringe • Weight: 9g or 3g • Automix tips, Eco-tips	• Delivery System: Syringe • Weight: 5g • Automix tips, Intraoral tips	Similar
Period of Use		Permanent	Permanent	Permanent	Same
Shelf-Life		2 years	2 years	18 months	Same

7.2. Comparison Chart

The subject device has the same indications for use and the technological characteristics as the predicate device. The minor raw materials are different between the devices but the performance and the biocompatibility test results show that it does not raise a concern in safety and effectiveness.

8. Non-Clinical Testing

- Performance Tests including
  - Appearance, Weight, Packaging, Sensitivity to ambient light, Colour stability, Film thickness, Working time, Setting time, Flexural strength, Water sorption, Solubility, Radiopacity, Bond strength, Dentinal tubule blocking efficacy in accordance with ISO 4049, ISO 29022.

- Biocompatibility Tests including
  - ISO 10993-1 Biological evaluation of medical devise – Part 1: Evaluation and testing within a risk management process
  - Cytotoxicity test - ISO 7405:2018, Dentistry-Evaluation of biocompatibility of medical devices used in dentistry
  - Irritation test - ISO 10993-23:2021, Tests for irritation
  - Acute systemic toxicity test - ISO 10993-11:2017, Tests for systemic toxicity
  - Skin sensitization test - ISO 10993-10:2021, Tests for skin sensitization

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

9. Conclusion

The subject device and the predicate device have the same intended use and have the same technological characteristics. Based on the similarities and the test results, we conclude that the subject device is substantially equivalent to the predicate device.