



December 19, 2025

Kulzer, LLC
% Dave Yungvirt
CEO
Third Party Review Group, LLC
7 Giralda Farms, Suite 120a
Madison, New Jersey 07940

Re: K254063
Trade/Device Name: iCEM Universal Plus
Regulation Number: 21 CFR 872.3275
Regulation Name: Dental cement
Regulatory Class: Class II
Product Code: EMA
Dated: December 17, 2025
Received: December 17, 2025

Dear Dave Yungvirt:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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
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

510(k) Number (if known)

K254063

Device Name

iCEM Universal Plus

Indications for Use (Describe)

Indications

- Bonding of indirect restorations made of composite, all-ceramic and metal.
- Bonding of prosthetic devices (crowns, inlays, onlays, bridges, and veneers) to cavities, abutment teeth, or implant abutments.
- Dental core bonding.

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.

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510(k) Summary – Abbreviated 510(k)

Date Prepared: 12/17/2025

Contact Details

Applicant Name: Kulzer, LLC

Applicant Address: 4315 S Lafayette Blvd South Bend, IN 46614 United States

Applicant Contact Telephone: (574) 335-9247

Applicant Contact: Mr. Lucas Harmon

Applicant Contact Email: lucas.harmon@kulzer-dental.com

Device Name

Device Trade Name: iCEM Universal Plus

Common Name: Dental cement

Classification Name: Cement, Dental

Regulation Number: 872.3275

Product Code(s): EMA

Legally Marketed Predicate Devices

Predicate #: K200798

Predicate Trade Name: G-CEM ONE

Product Code(s): EMA

Device Description Summary

The subject device is a dual-cure resin cement for dental adhesion composed of two types of paste: the Catalyst Paste and the Base Paste. Each paste is filled separately in the independent double-barrel syringe and is mixed and dispensed through a dedicated mixing tip attached to the syringe nozzle. To match the color of the prepared tooth structure (dentin and enamel) and the prosthetic restoration, the Base Paste is available in four shades: Translucent, Yellow, White, and Opaque. The accessory tips include iCEM Universal Plus Mixing Tips and iCEM Universal Plus Endo Tips (consisting of Endo Mixing Tips and Extension Tips), which differ in tip diameter and are selected according to the clinical indication. All tips are single-use only. The mixed resin cement cures through both chemical and light polymerization. The subject device can adhere to tooth structure (dentin and enamel) using iCEM Universal Plus Cement, with or without the use of iCEM Universal Plus Primer, depending on the clinical indication:

- Self-Adhesive Mode: Using only iCEM Universal Plus Cement as a self-adhesive resin cement.

- Adhesive Mode: Using iCEM Universal Plus Cement in combination with the dedicated primer, iCEM Universal Plus Primer, as an adhesive resin cement.

When used in the adhesive mode, iCEM Universal Plus Primer contains a portion of the polymerization initiators involved in the chemical polymerization of the subject device. Upon contact with the subject device, these initiators are activated, initiating the polymerization of the monomers and resulting in curing. This combination enhances the bond strength to tooth structure (dentin and enamel) compared to the Self-Adhesive Mode.

Intended Use/Indications for Use

- Bonding of indirect restorations made of composite, all-ceramic and metal.
- Bonding of prosthetic devices (crowns, inlays, onlays, bridges, and veneers) to cavities, abutment teeth, or implant abutments.
- Dental core bonding.

Indications for Use Comparison

There is no difference in the indication for use between the subject device and the predicate device (G-CEM ONE: K200798) aside from verbiage, and they are substantially equivalent.

Technological Comparison

There are technical differences in the operating procedures between the subject device and the predicate device. iCEM Universal Plus allows surface treatment to both tooth and prosthesis with a single primer. Other differences are due to variations in the time required for application, curing, etc. and do not affect performance or safety. Both devices have identical indications for use, with no differences in their clinical applicability. The technical differences arise from variations in the method of use and product configuration, while the fundamental functions required to achieve the intended use remain the same.

Therefore, it is concluded that the subject device is substantially equivalent to the predicate device.

	Kulzer North America	GC America Inc.	Identified Differences
Product Name	iCEM Universal Plus Cement	G-CEM ONE	-
Product Code	EMA	EMA	-
510(k) Number	—	K200798	-
Indications for Use	<p><u>Use of Cement in Adhesive Mode with Primer</u></p> <ul style="list-style-type: none"> • Cementation of all types of all-ceramic, resin and metal-based inlays, onlays, crowns, bridges and veneers. • Cementation of metal, ceramic, fiber posts, and cast post and cores. • Cementation of all-ceramic, composite or metal restorations on implant abutments. <p><u>Use of Cement in Self-Adhesive Mode</u></p> <ul style="list-style-type: none"> • Cementation of zirconia and metal-based inlays, onlays, crowns and bridges. • Cementation of metal posts and cast cores. • Cementation of zirconia, metal-based restorations on implant abutments. 	<ol style="list-style-type: none"> 1. Cementation of all types of all ceramic, resin and metal-based inlays, onlays, crowns and bridges. 2. Cementation of metal, ceramic, fiber posts, and cast post and cores. 3. Cementation of all ceramic and composite veneers. 4. Final cementation of crowns and bridges on implant abutments. 	Minor difference in verbiage.
Contraindications	<p><u>For Cement & Primer</u></p> <ul style="list-style-type: none"> • Cement and Primer contains methacrylate resins and Primer contains ethanol. Cement and Primer are not for use on or by persons who has a history of severe allergic reactions to this 	<ol style="list-style-type: none"> 1. Direct pulp capping. 2. Avoid use of this product in patients with known allergies to methacrylate monomer, methacrylate polymer or ethanol. <p>*Referred by IFU</p>	<p>Minor difference in verbiage.</p> <p>The IFU of iCEM also instructs users to perform pulp protective measures when using the medical device in close proximity to pulp.</p>

	<p>product, methacrylate monomers and ethanol.</p> <p>For Tips</p> <p>Mixing tips or Mixing Tips for End is a single-use disposable tips and dispose it after each patient to avoid cross-contamination.</p>		
Cement Shades	<p>Translucent Yellow White Opaque</p>	<p>Translucent A2 (Vita® shade) White opaque AO3 (opaque)</p>	<p>Both iCEM and G-CEM ONE are the same in that they have a lineup of four shades for cement. Although the shade names differ, they share the same characteristics.</p>
Biocompatibility	<p>A biocompatibility assessment was completed according to ISO 10993-1:2018, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process.</p> <p>Biocompatibility of iCEM Universal Plus Cement is acceptable device from the biological evaluation result.</p>	<p>A biocompatibility assessment was completed according to ISO 10993-1:2009, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process.</p> <p>Biocompatibility of G-CEM ONE is acceptable device from the biological evaluation result.</p>	-
Software	No software utilized for the device.	No software utilized for the device.	-

Non-Clinical and/or Clinical Tests Summary & Conclusions

Testing conducted on the subject device was based on the performance criteria outlined in the guidance document titled “Dental Cements - Performance Criteria for Safety and Performance Based Pathway: Guidance for Industry and Food and Drug Administration Staff,” issued on September 30, 2024. Additional non-clinical testing was conducted utilizing ISO 4049:2019 and ISO 9917-1.

Bond strength was tested to the specifications outlined in “Dental Cements - Performance Criteria for Safety and Performance Based Pathway: Guidance for Industry and Food and Drug Administration Staff.” The bond strength testing for iCEM Universal Plus, both in Adhesive Mode and Self-Adhesive Mode, indicated acceptable values and met the specifications set in the performance criteria guidance.

Additional non-clinical testing was performed utilizing ISO 4049:2019, including flexural strength, film thickness, working time, setting time, x-ray opacity, water absorption, and solubility. All testing for iCEM Universal Plus indicated acceptable values and met the specifications and criteria set in the ISO 4049:2019 standard.

Compressive strength was tested to the specifications outlined in ISO 9917-1. The testing for iCEM Universal Plus indicated acceptable values and met the specifications and criteria set in the ISO 9917-1 standard.

Clinical testing is not applicable for this device.

Conclusion

iCEM Universal Plus is substantially equivalent to G-CEM ONE (K200798) with respect to intended use and technological characteristics. Performance testing demonstrates comparable safety and effectiveness to FDA guidance documents and ISO standards; no new questions are raised.