May 18, 2026

GC America, Inc.
Futoshi Fusejima
Director of PE & Regulatory Affairs
3737 W. 127th St.
Alsip, Illinois 60803

Re: K254109
Trade/Device Name: G-CEM Universal
Regulation Number: 21 CFR 872.3275
Regulation Name: Dental Cement
Regulatory Class: Class II
Product Code: EMA
Dated: April 24, 2026
Received: April 24, 2026

Dear Futoshi Fusejima:

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,

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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K254109

Please provide the device trade name(s).

G-CEM UNIVERSAL

Please provide your Indications for Use below.

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.

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

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

1. SUBMITTER

GC America Inc.
3737 W. 127th Street
Alsip, IL 60803

Contact Person: Futoshi Fusejima
Phone: (708) 926-3050
Alternate Contact: Tamiko Scott
Phone: (708) 926-3261
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Date Prepared: May 15, 2026

2. DEVICE

Name of Device: G-CEM Universal
Common Name: Dental cement
Classification Name: Cement, Dental (21 CFR 872.3275)
Regulatory Class: Class II
Product Code: EMA

3. PREDICATE DEVICE

Product	Applicant	510(k) No.	Code No.	Predicate	Decision Date
G-CEM ONE	GC America Inc.	K200798	EMA	Primary	11/24/2020

4. DEVICE DESCRIPTION

G-CEM Universal is a dual-cure, self-adhesive resin cement that can be optionally used in combination with the tooth or other indirect restoration primer. The mixed cement is hardened through polymerization. The adhesive component is an acidic monomer which also can polymerize with frame-forming monomers. This copolymerizing reaction provides higher physical strength than resin-modified glass ionomer cements.
Furthermore, applying the primer to the cavity, abutment tooth, or other indirect restorations modifies the surface and/or initiates the polymerization of both the cement and the primer, resulting in stable adhesion. The components consist of Paste A and B, which are filled in a one-body syringe. Both pastes are automixed with a mixing tip and directly applied to restorations or the prepared cavity.

5. INDICATIONS FOR USE

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.

There are no substantial differences between the applicant device and the primary device in indications for use, and there are no differences in the safety and effectiveness of the device when used as labeled.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Applicant device and predicate device are substantially equivalent in the following points.

- Polymer-based dual-cure, self-adhesive resin cement used for cementation.
- The curing mechanism is polymerization of uncured methacrylate ester monomers. This reaction is caused by polymerization initiators and photo-initiator system.
- The adhesive component is an acidic monomer which also can polymerize with frame-forming monomers. This copolymerizing reaction provides higher physical strength than resin-modified glass ionomer cements.
- Can be optionally used in combination with the tooth surface primer to promote the self-adhesion to the tooth structure.
- Can be optionally used in combination with the indirect restoration surface primer to promote the self-adhesion to the indirect restorations made of zirconia or metal.
- Complies with all the requirements of ISO 4049: 2019 Dentistry - Polymer-based restorative materials.
- Shows substantially equivalent performance when tested based on the FDA guidance document entitled “Dental Cements – Performance Criteria for Safety and Performance Based Pathway - Guidance for Industry and Food and Drug Administration Staff”.

The following difference may be noted between applicant device and predicate devices.

- The applicant device does not include a primer.
- The use of primer on indirect restorations made of glass-ceramic or composite resin is optional for the applicant device; however, it is mandatory for predicate device to provide self-adhesion.
- Contrast agents have been added to the applicant device to enhance radiopacity, and UV absorbers have been added to improve color stability.

7. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Mechanical testing
It is confirmed that the device conforms to the required specifications based on FDA guidance document entitled “Dental Cements – Performance Criteria for Safety and Performance Based Pathway - Guidance for Industry and Food and Drug Administration Staff” and ISO 4049:2019 Dentistry – Polymer-based restorative materials, Type 2, Class 3.
Performance testing includes:

- Film thickness
- Working time
- Setting time
- Flexural strength
- Water sorption
- Solubility

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- Colour stability after irradiation and water sorption
- Radio-opacity
- Adhesive bond Strength
- Ion release profile

Biocompatibility testing
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, and ISO 7405:2025 Dentistry – Evaluation of biocompatibility of medical devices used in dentistry.
G-CEM Universal is a dual-cure self-adhesive resin cement, so medical device categorization by ISO 10993 for biological evaluation of medical devices is as follows.

Category	: Externally communicating medical device
Contact	: Tissue / bone / dentin
Contact duration	: Long term (> 30 d)

In conclusion, biocompatibility of G-CEM Universal is an acceptable device from the biological evaluation result.

Cytotoxicity (CYTOTOXICITY TEST)
Based on the criteria of the protocol of ISO 10993-5

Irritation or intracutaneous reactivity (INTRACUTANEOUS REACTIVITY)
Based on the criteria of the protocol of ISO 10993-23

Pyrogenicity (RABBIT PYROGEN TEST)
Based on the criteria of the protocol of ISO 10993-11

Acute systemic toxicity
Based on the criteria of the protocol of ISO 10993-11

Genotoxicity toxicity (BACTERIAL REVERSE MUTATION TEST, In Vitro MICRONUCLEUS TEST and MICRONUCLEUS TEST in MICE)
Based on the criteria of the protocol of ISO 10993-3

8. CONCLUSIONS

Based on similarities in indications for use, technology, safety and effectiveness, the applicant device is substantially equivalent to the predicate devices.

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