September 19, 2025

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

Re: K250953
Trade/Device Name: EQUIA LC ONE
Regulation Number: 21 CFR 872.3275
Regulation Name: Dental Cement
Regulatory Class: Class II
Product Code: EMA, EBF
Dated: August 22, 2025
Received: August 22, 2025

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 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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K250953

Please provide the device trade name(s).

EQUIA LC ONE

Please provide your Indications for Use below.

Indications for Use:
1. Class I, II, III, IV and V restorations
2. Root surface restoration
3. Core build-up

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

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

K250953 510(k) Summary

1. Submitter Information:

GC America Inc.
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Alsip, IL 60803

Contact Person: Futoshi Fusejima
Phone: (708) 926-3050
Alternate Contact: Tamiko Scott
Phone: (708) 926-3261
Fax: (708) 925-0373

Date Prepared: September 18, 2025

2. Device Name:

Proprietary Name: EQUIA LC ONE
Common Name: Dental cement
Classification Name: Cement, Dental
Device Classification: Class II, 872.3275/872.3690
Product Code: EMA/EBF

3. Predicate Devices:

Product	Applicant	510(k) No.	Code No.	Predicate	Decision Date
Pulpdent ACTIVA BioACTIVE RESTORATIVE (Pulpdent RMGI Fill)	Pulpdent Corporation	K130223	EMA	Primary	03/29/2013
GC Fuji Automix LC (GC Fuji Direct)	GC America Inc.	K172382	EMA	Reference	04/02/2018
Fuji II LC Capsule	GC America Inc.	K993973	EBF	Reference	01/11/2000

4. Description of Device:

EQUIA LC ONE is a resin-modified glass ionomer dental restorative material which is intended to be used as a restorative filling material for direct restorations and or core buildups. The applicant device is provided as a powder/liquid formulation in a mixing capsule.

5. Indications for Use:

1. Class I, II, III, IV and V restorations
2. Root surface restoration
3. Core build-up

The verbiage describing the Indications for Use in the primary predicate device (Pulpdent RMGI FILL), regarding restorations (namely: "as filling material in dental restorations") describes a much broader field than the Indications for Use in the subject product, in point 1 and 2. In addition, the primary device clarifies in its IFU that Class I, II, III, IV and V restoration and root surface restoration are its indication. Therefore, the applicant device's indications for use point 1 and 2 are substantially equivalent to the indications for use of the primary predicate device.

The applicant device's indications for use point 3 is the same as the indications for use point 3 of the

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reference device 1 (GC Fuji Automix LC).

In conclusion, there are no substantial differences between the applicant device and the primary or reference 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 Technology:

The technological principles of the applicant device as a resin modified glass ionomer dental restorative material are similar to those of predicate devices. The paste is cured by chemical reaction between the fluoro-alumino-silicate glass and the polycarboxylic acid aqueous solution, and polymerization of the monomer. In addition, carboxylate group of polyacrylic acid makes chemical bonds to calcium on the tooth surface.
In conclusion, the applicant device is substantially equivalent to the predicate devices in techno-logical principle.

7. Performance Bench Tests:

It is confirmed that the device conforms to the required specifications of ISO 9917-2:2017 Dentistry – Water-based cements – Part 2: Resin-modified cements, Class 3, Restoration, including for tooth core build-up.
Performance testing includes:

- Appearance
- Working time
- Setting time
- Flexural strength
- Radio-opacity
- Shade and colour stability
- Flexural modulus
- Compressive strength
- Diametral tensile strength
- Light cure set time
- Self-cure set time
- Share bond strength
- Polymerization shrinkage
- Residual methyl methacrylate monomer testing
- Fluoride Ion Release Profile

8. Biocompatibility:

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.
EQUIA LC ONE is a bulk fill resin reinforced glass hybrid restorative. 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 EQUIA LC ONE is an acceptable device from the biological evaluation result.

Cytotoxicity (L929 MEM ELURION TEST)
Based on the criteria of the protocol of ISO 10993-5

Sensitization (KLIGMAN MAXIMIZATION TEST)
Based on the criteria of the protocol of ISO 10993-10

Intracutaneous reactivity (INDIRECT PRIMARY ORAL (BUCCAL) IRRITATION TEST)
Based on the criteria of the protocol of ISO 10993-23

Acute systemic toxicity (SYSTEMIC INJECTION TEST)
Based on the criteria of the protocol of ISO 10993-11 and ISO 10993-12

Pyrogenicity (RABBIT PYROGEN TEST)
Based on the criteria of the protocol of ISO 10993-11 and ISO 10993-12

Subacute systemic toxicity (Subacute systemic toxicity in Rats)
Based on the criteria of the protocol of ISO 10993-11 and ISO 10993-6

Genotoxicity toxicity (REVERSE MUTATION TEST and CHROMOSOMAL ABERRATION TEST)
Based on the criteria of the protocol of ISO 10993-3 and ISO 10993-12

9. Conclusion:

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