October 2, 2025

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

Re: K251124
Trade/Device Name: G-Bond Universal
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: Class II
Product Code: KLE, EBC
Dated: October 1, 2025
Received: October 1, 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.	K251124

Please provide the device trade name(s).

G-Bond Universal

Please provide your Indications for Use below.

Indications for Use:
1. Direct bonding of restorative materials
2. Bonding of dual-cured core build up composites
3. Adhesive cementation of indirect restorations
4. Priming of adherent surface of indirect restorations
5. Intraoral repair of fractured restorations
6. Treatment of hypersensitive teeth
7. Sealing of tooth preparation (cavity or abutment) for indirect restorations
8. Treatment of exposed root surfaces
9. Micro-invasive treatment and infiltration of non-cavitated non-carious enamel lesions
10. Post cementation

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)

Section 5 – 510(k) Summary

1. Submitter Information:

GC America Inc.
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Alsip, IL 60803

Contact Person: Futoshi Fusejima
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Alternate Contact: Tamiko Scott
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Date Prepared: August 29, 2025

2. Device Name:

Proprietary Name: G-BOND Universal
Common Name: Resin tooth bonding agent
Classification Name: Agent, Tooth Bonding, Resin, Pit and fissure sealant and conditioner
Device Classification: Class II, 872.3200
Product Code: KLE/EBC

3. Predicate Devices:

Product	Applicant	510(k) No.	Code No.	Predicate	Decision Date
G-Premio BOND	GC America Inc.	K143140	KLE	Primary	04/20/2015
Icon (INFILTRATION KIT)	DMG USA, Inc	K100062	EBC	Secondary	03/26/2010
Scotchbond Universal Plus Adhesive (ADH19)	3M Deutschland GmbH ESPE Platz	K192961	KLE	Reference	10/31/2019

4. Description of Device:

G-BOND Universal is a one component, light-cured bonding agent, which can also be used for micro-invasive treatment and infiltration of non-cavitated non-carious enamel lesions, available in a 5 mL liquid bottle or 0.1 mL unit dose.

5. Indications for Use:

1. Direct bonding of restorative materials
2. Bonding of dual-cured core build-up composites
3. Adhesive cementation of indirect restorations
4. Priming of adherent surface of indirect restorations
5. Intraoral repair of fractured restorations
6. Treatment of hypersensitive teeth
7. Sealing of tooth preparation (cavity or abutment) for indirect restorations
8. Treatment of exposed root surfaces
9. Micro-invasive treatment and infiltration of non-cavitated non-carious enamel lesions
10. Post cementation

The indications as dental adhesive system is covered with primary predicate and reference device. The indication as a treatment agent of hypersensitive teeth is covered with primary predicate and refer-ence device.
The indication as a micro-invasive treatment and infiltration agent of non-cavitated non-carious enamel lesions is covered with secondary predicate device.

In conclusion, there are no substantial differences between the applicant device and predicate or reference devices 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 dental adhesive system are similar to those of predicate devices G-Premio BOND and Scotchbond Universal Plus Adhesive, as follows:

1. The product demineralizes the tooth substance and simultaneously penetrates the monomer component, which then photopolymerizes through photopolymerization and bonds to the tooth tissue.
2. The phosphate ester monomer bonds with the tooth structure metal, zirconia, and alumina surfaces, thereby bonding to metal, zirconia, and alumina.
3. The silane coupling agent bonds with the surfaces of porcelain, lithium disilicate glass, and composite resins, thereby bonding to porcelain, lithium disilicate glass, and composite resins.
4. The product demineralizes the tooth substance and monomer component simultaneously penetrates the tooth substance. The product is then bonded and hardened using dental adhesive resin cement, thereby bonding to the tooth tissue.
5. The product penetrates the dentinal tubules of the formed cavity and abutment teeth, etc., and photopolymerizes, then it seals them.

The technological principle of the applicant device as a treatment agent of hypersensitive teeth is similar to the predicate device G-Premio BOND, as follows:

1. The product penetrates the dentinal tubules exposed by hypersensitivity, and photopolymerizes, then it suppresses hypersensitivity by sealing the dentinal tubules.

The technological principle of the applicant device as a micro-invasive treatment and infiltration agent of non-cavitated non-carious enamel lesions is similar to that of the predicate device Icon, as follows:

1. The infiltration mechanism is applying it to white spot lesions (WSL) of enamel substance, then penetrating the tooth structure and adhering chemically and mechanically by photopolymerization of uncured resin monomers.

In conclusion, the applicant device is substantially equivalent to the predicate devices in technological principle.

7. Performance Bench Tests:

Since there is no international standard, such as ISO, the physical properties of this product were established based on Japanese certification criteria of “Dental dentin adhesive”, “Dental metal adhesive material”, “Dental ceramics adhesive”, “Dental hypersensitive dentine desensitizer”, “Dental sealing/coating material” and “Tooth surface coating material.” Additionally, the degree of material penetration when used for infiltrant applications and the viscosity were also tested to confirm the substantial equivalence of the applicant device with predicate devices in terms of safety and effectiveness.

Performance testing includes:

- Appearance
- Curing property
- Hardness

- Bond strength
- Application characteristics
- Sealing property of dentin tubules
- Infiltration performance
- Viscosity

8. Biocompatibility:

A biocompatibility assessment was completed according to ISO 10993-1:2018 and ISO 7405:2018.
G-BOND Universal is a universal adhesive, 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)

Therefore, biological evaluation tests are planned taking account of the requirements of ISO 10993-1: 2018 ANNEX A and the tests in Table 5.2 are selected and discussed as the results of consideration for the device and its contact to body parts or ingredients.

Table 5.2. Biocompatibility evaluation on ISO 10993-1: 2018 ANNEX A

	Evaluation tests for consideration
1	Cytotoxicity
2	Sensitization
3	Irritation or intracutaneous reactivity
4	Material mediated pyrogenicity
5	Acute systemic toxicity
6	Subacute toxicity
7	Subchronic toxicity
8	Chronic toxicity
9	Implantation effects
10	Genotoxicity
11	Carcinogenicity

Furthermore, in addition to the above test, according to ISO 7405:2018 ANNEX A, the test to be considered for evaluation of biocompatibility shown in Table 5.3 is listed.

Table 5.3. Biocompatibility evaluation on ISO 7405:2018 ANNEX A

	Evaluation tests for consideration
12	Pulp and dentine usage test

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

9. Conclusion:

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