August 29, 2025

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

Re: K251946
Trade/Device Name: G aenial Universal Injectable II
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: Class II
Product Code: EBF, EMA, EBC, DYH
Dated: June 18, 2025
Received: June 25, 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,

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.	K251946

Please provide the device trade name(s).

G aenial Universal Injectable II

Please provide your Indications for Use below.

1. Direct restorative for Class I, II, III, IV, and V cavities
2. Fissure sealant
3. Sealing hypersensitive areas
4. Repair of (in)direct aesthetic restorations, temporary crown & bridge, defect margins when margins are in enamel
5. Blocking out undercuts
6. Liner or base
7. Core build-up
8. Adhesive cementation of ceramic and composite veneers, inlays and onlays with a thickness (<2.0 mm) and translucency that enables the complete light curing of the cement
9. Retention of aligner e.g. by fabrication of aligner attachments

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.
3737 W. 127th Street
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: Aug 21, 2025

2. Device Name:

Proprietary Name: G-ænial Universal Injectable II
Common Name: Tooth shade resin material
Classification Name: Material, Tooth Shade, Resin,
Cement, dental,
Sealant, Pit And fissure And Conditioner,
Adhesive, Bracket And Tooth Conditioner, Resin
Device Classification: Class II, 872.3690, 872.3275, 872.3765, 872.3750
Product Code: EBF/EMA/EBC/DYH

3. Predicate Devices:

Product	Applicant	510(k) No.	Code No.	Predicate	Decision Date
Nmf004a (G-ænial Universal Injectable)	GC America Inc.	K173500	EBF	Primary	03/08/2018
G-Cem LinkForce, Dual Cure Activator, Try-In Paste, Multi Primer	GC America Inc.	K153231	EMA	Secondary	07/06/2016
AlignerFlow LC	Voco GmbH	K231817	DYH	Additional	12/01/2023

4. Description of Device:

G-ænial Universal Injectable II is a light-cured, nano-filled radiopaque composite resin filled in syringe. The device is used for the restoration of both anterior and posterior teeth, core build-up, adhesive cementation of ceramic and composite veneer, inlays and onlays, and build-up for transparent removable orthodontic retainers. The device is available in 9 shades.

5. Indications for Use:

1. Direct restorative for Class I, II, III, IV and V cavities
2. Fissure sealant
3. Sealing hypersensitive areas
4. Repair of (in)direct aesthetic restorations, temporary crown & bridge, defect margins when margins are in enamel
5. Blocking out undercuts
6. Liner or base

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7. Core build-up
8. Adhesive cementation of ceramic and composite veneers, inlays and onlays with a thickness (<2.0 mm) and translucency that enables the complete light curing of the cement
9. Retention of aligner e.g. by fabrication of aligner attachments

6. Comparison of Technology:

G-ænial Universal Injectable II is a dental composite consisting of cross-linked polymeric material reinforced by a dispersion of glass filler particles bonded to the resin matrix. The product contains a photo initiator to allow for curing/conversion. The end result is a conversion from a paste to a hard, solid material. It is initially placed in a dental cavity prepared by a dental professional. The cavity restoration is pretreated with a bonding agent. Following the bonding agent, G-ænial Universal Injectable II is placed, sculpted and then polymerized using a light curing device. The dental professional can then add more material, polymerize and polish for a clinical result. G-ænial Universal Injectable II and Nmf004a and AlignerFlow LC consist of similar compositions and cure by same light-curing. This allows G-ænial Universal Injectable II to be used for direct restoration, core build-up, and aligner attachment fabrication, as well as Nmf004a and AlignerFlow LC. In addition, although the curing mechanism is different from G-CEM LinkForce, the material cures by curing reaction and are used as an adhesive for cementing composite veneer, inlays and onlays.

Substantial equivalence table and performance comparison table are shown in table 5.1 and 5.2.

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

Table 5.1 Substantial equivalence to the comparative device

	Applicant device	Primary predicate device	Secondary predicate device	Additional predicate device	Rationale
Trade name	G-ænial Universal Injectable II	Nmf004a (G-ænial Universal Injectable) K173500	G-Cem LinkForce, Dual Cure Activator, Try-In Paste, Multi Primer K153231	AlignerFlow LC K231817	
Manufacturer	GC Corporation	GC Corporation	GC Corporation	Voco GmbH	
Product category	EBF/EMA/EBC/DYH Material, Tooth shade, Resin, Cement, Dental, Sealant, Pit And fissure And Conditioner, Adhesive, Bracket And Tooth Conditioner, Resin, Class II	EBF Material, Tooth shade, Resin, Class II	EMA Cement, Dental, Class II	DYH Adhesive, Bracket And Tooth Conditioner, Resin, Class II	Applicant device and primary device are the same. Reference device is different in that the classification name.

Indications for use	1. Direct restorative for Class I, II, III, IV and V cavities 2. Fissure sealant 3. Sealing hypersensitive areas 4. Repair of (in)direct aesthetic restorations, temporary crown & bridge, defect margins when margins are in enamel 5. Blocking out undercuts 6. Liner or base 7. Core build-up 8. Adhesive cementation of ceramic and composite veneers, inlays and onlays with a thickness (<2.0 mm) and translucency that enables the complete light curing of the cement 9. Retention of aligner e.g. by fabrication of aligner attachments	1. Liner or base 2. Blocking out undercuts 3. Repair of (in) direct aesthetic restorations, temporary crown & bridge, defect margins when margins are in enamel 4. Sealing hypersensitive areas 5. Fissure sealant 6. Direct restorative for Class I, II, III, IV, V cavities 7. Core build-up	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 (up to 2 teeth). 4. Permanent cementation of crowns and bridges on implant abutments.	1. Retention of aligner e.g. by fabrication of aligner attachments 2. Bonding of lingual retainers 3. Occlusal build-ups	Indication 1 to 7 are identical to the primary device. The indication as adhesive cement is covered with the reference device 1. Applicant device and reference device 2 are substantially equivalent because they have the same cementation mechanism with bonding material. The indication as orthodontic retainer is covered with reference device 2.

Product description	G-ænial Universal Injectable II is a light-cure, radio-opaque restorative material to be used intra-orally and classified as a Type 1 and Class 2 (Group 1) per ISO standard 4049, a light-cure, radio-opaque luting material to be used intra-orally and classified as a Type 2 and Class 2 (Group 1) per ISO standard 4049, and a light-cure material for aligner attachment. This material has a radiopacity equivalent to 2.5 - 3.0 mm of aluminum (dentine = 1 mm, enamel = 2 mm). The particle size of inorganic fillers range is 0.01 - 0.5 µm. The total amount of inorganic filler is approximately 46 vol%.	G-æniall Universal Injectable is a light-cure, radioopaque restorative material to be used intra-orally and classified as a Type 1 and Class 2 (Group 1) per ISO standard 4049. This material has a radiopacity equivalent to 2.5 - 3.0 mm of aluminum (dentine = 1 mm, enamel = 2 mm). The particle size of inorganic fillers range is 0.01 - 0.5 µm. The total amount of inorganic filler is approximately 46 vol%. .	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.	AlignerFlow LC is a flowable, light-curing and fluorescent nanohybrid composite for aligner attachments within the scope of aligner treatments. AlignerFlow LC contains 83% by weight inorganic fillers and is used with a dentin enamel bond.	Applicant device and primary device are the same. Aplplicant device and reference device are substantially equivalent as materials for cementation and attachment applications.
Classification of material	Light-cured resin composite	Light-cured resin composite	Dual-cured adhesive resin cement	Light-cured resin composite for aligner attachments	Applicant device, primary device and reference device 2 are the same. Although applicant device and reference device 1 are different in mechanism of curing, these are substantially equivalent in terms of curing.
Delivery form	Paste in a syringe	Paste in a syringe	Paste-paste formulation in a double-chamber syringe	Paste in a syringe	The delivery form of the applicant device is the same as the primary device.

Chemical composition	Barium glass, dimethacrylate, initiator, pigment, silicon dioxide, stabilizer	Barium glass, dimethacrylate, initiator, pigment, silicon dioxide, stabilizer	Barium glass, dimethacrylate, initiator, pigment, silicon dioxide, stabilizer	Barium alminium borosilicate glass, silicon dioxide, DDDMA, BisGMA, TEGDMA, BisEMA, fumed silica, initiators, stabilisers, pigments	All devices are substantially equivalent.
Curing mode	Light-curing	Light-curing	Light-curing and self-curing	Light-curing	No difference between the applicant device and the primary device.
Sterilization	No sterilization	No sterilization	No sterilization	No sterilization	All devices are no sterilization
Storage temperature	4 – 25	4 – 25	2 – 8	4 – 28	Applicant device, primary device, and reference device 2, which are light-cures, are substantially equivalent. Reference device 1 has a lower storage temperature than the other device because of dual-cure.
Shelf life	3 years	3 years	2 years	N.D.	The shelf life of applicant device is the same as that of the primary device.
Available shades	A1, A2, A3, A3.5, B1, UE (Enamel shade), BW (Bleach shade), U<Bulk> and UO (Opaque shade)	A1, A2, A3, A3.5, A4, B1, B2, CV, CVD, AO1, AO2, AO3, JE, AE, XBW, BW	Translucent (clear translucent), A2 (A2 translucent), Bleach (bleach opaque), Opaque (universal opaque)	A1, A2, A3	A1, A2, A3, A3.5, B1, UE, BW, UO of applicant device are equivalent to those of primary device. U<Bulk> of applicant device is same use as A shades of applicant device.

Direction for use	(A) DIRECT RESTORATION PROCEDURE 1. SHADE SELECTION 2. CAVITY PREPARATION 3. BONDING TREATMENT 4. PLACEMENT OF G-ænial Universal Injectable II 5. LIGHT CURING 6. FINISHING AND POLISHING (B) CEMENTATION PROCEDURE 1. REMOVAL OF THE TEMPORARY RESTORATION 2. TREATMENT OF THE SUFFICIENTLY TRANSLUCENT RESTORATION 3. TREATMENT OF THE TOOTH PREPARATION 4. CEMENTATION 5. FINAL POLISHING (C) PROCEDURE FOR TRANSPARENT, REMOVABLE ORTHODONTIC RETAINERS 1. TEETH PREPARATION 2. PLACEMENT OF G-ænial Universal Injectable II ON THE TRANSFER TRAY 3. BUILD UP ATTACHMENT ON TEETH 4. REMOVE ATTACHMENT	1. Shade Selection 2. Cavity Preperation 3. Bonding Treatment 4. Placement of G-ænial Universal Injectable 5. Light-Cureing 6. FINISHING AND POLISHING	A. CEMENTATION TECHNIQUE for all inlays, onlays, crowns, bridges and veneers 1. TRY-FIT OF THE RESTORATION 2. PRE-TREATMENT OF THE RESTORATION 3. PRE-TREATMENT OF THE PREPARATION 4. DISPENSING 5. CEMENTATION 6. EXCESS CEMENT REMOVAL 7. FINAL SET 8. FINAL POLISHING AND ADJUSTMENTS B. CEMENTATION TECHNIQUE for metal, ceramic, fiber posts, and cast post and cores 1. PRE-TREATMENT OF THE POS 2. TOOTH PREPARATION 3. DISPENSING & CEMENTATION 4. EXCESS CEMENT REMOVAL	Preparation: Bonding materials: Application: a) Fabrication of aligner attachments/Retention of aligners Apply AlignerFlow LC directly into corresponding recesses of the attachment template. Insert the attachment template into the mouth and cure each attachment through the transparent template. Once the aligner treatment is completed, the attachments can be removed using a grinding/finishing diamond burr. Subsequent polishing of the tooth surface is then recommended. b) Attachment of lingual retainers Place the prefabricated retainer wire in the desired position on the tooth surfaces, fixing in place temporarily if necessary, and apply AlignerFlow LC to the wire and surreounding tooth surfaced. Cover the ends of the wire with AlignerFlow LC too. Cure each applied portion of the material separately. c) Occlusal build-ups In principle, the preparation of dental hard tissue should follow the rules for afhesive restorative treatment; preparation should be minimally invasive in order to protect healthy dental hard tissue. Apply AlignerFlow LC in layers of no more than 2 mm thickness and then light-cure. Light-curing:	Direction for use of applicant device is substantially equivalent to that of the predicate devices.

Table 5.2 Performance comparison table

Property	Requirement	G-ænial Universal Injectable II	Nmf004a	G-CEM LinkForce	AlignerFlow LC
		EBF/EMA/EBC/DYH	EBF	EMA	DYH
Film thickness	50 μm or less.	Complies		Complies	
Sensitivity to light	Remain physically homogeneous.	Complies	Complies	Complies	Complies
Depth of cure (ISO 4049)	Opaque shade; 1.0 mm or more Other shade; 1.5 mm or more	Complies	Complies		Complies
Flexural strength	80 MPa or more.	Complies	Complies	Complies	Complies
Water sorption	40 $\mu g/mm^3$ or less	Complies	Complies	Complies	Complies
Solubility	7.5 $\mu g/mm^3$ or less	Complies	Complies	Complies	Complies
Shade of restoration materials	Closely match the shade of the shade guide. Shall be evenly pigmented.	Complies	Complies	Complies	Complies
Colour stability of after irradiation and water sorption	No more than slight change in colour.	Complies	Complies	Complies	Complies
Radio-opacity	Equal to or greater than the radio-opacity of the same thickness of aluminium.	Complies	Complies	Complies	Complies
Depth of cure (ISO 6874)	1.5 mm or more	Complies	Complies		
Compressive strength	100 MPa or more.	Complies	Complies		
Elastic modulus	Equivalent or more than predicate device.	Complies	Complies		
Surface hardness	Equivalent or more than predicate device.	Complies	Complies		
Adhesive bond strength	Equivalent or more than predicate device.	Complies		Complies	

7. Performance Bench Tests:

It is confirmed that the device conforms to the required specifications based on FDA guidance document entitled "Dental Composite Resin Devices - Premarket Notification [510(k)] Submissions - Guidance for Industry and FDA Staff", "Dental Cements – Performance Criteria for Safety and Performance Based Pathway", ISO 4049:2019 Dentistry – Polymer-based restorative materials (Type 1 and 2, Class 2, Group 1), and ISO 6874:2015 Dentistry – Polymer-based pit and fissure sealants (Class 2)
Performance testing includes:

- Film thickness
- Sensitivity to light
- Depth of cure
- Flexural strength
- Water sorption
- Solubility
- Shade of restoration materials
- Colour stability of after irradiation and water sorption
- Radio-opacity
- Compressive strength
- Elastic Modulus
- Surface hardness
- Adhesive bond strength
- Filler particle size

8. Non-Clinical Performance 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 7405:2018 Dentistry – Evaluation of biocompatibility of medical devices used in dentistry.
G-ænial Universal Injectable II is a light-cured resin composite, 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-ænial Universal Injectable II is an acceptable device from the biological evaluation result.

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

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

Irratation or intracutaneous reactivity(ORAL MUCOSA IRRITATION TEST)
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

Subchronic systemic toxicity (Subchronic Systemic Toxicity Test by Subcutaneous Implantation)
Based on the criteria of the protocol of ISO 10993-11 and ISO 10993-6

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

9. Conclusion:

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