November 24, 2020

GC America Inc.
Mark Heiss
Director, Regulatory & Academic Affairs
3737 W. 127th Street
Alsip, Illinois 60803

Re: K200798
Trade/Device Name: G-CEM ONE
Regulation Number: 21 CFR 872.3275
Regulation Name: Dental Cement
Regulatory Class: Class II
Product Code: EMA
Dated: March 23, 2020
Received: March 26, 2020

Dear Mark Heiss:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

For Srinivas “Nandu” Nandkumar, Ph. D.
Director
DHT1B: Division of Dental Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Section 4 – Indications for Use

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200798

Device Name
G-CEM ONE

Indications for Use *(Describe)*

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.

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 - K200798

1. Submitter Information:

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

Contact Person: Mark Heiss, D.D.S.
Phone: (708) 926-3090
Alternate Contact: Lori Rietman
Phone: (708) 926-3092
Fax: (708) 925-0373

Date Prepared: March 23, 2020

2. Device Name:

Proprietary Name: G-CEM ONE
Classification Name: Dental cement
Device Classification: Class II, 872.3275
Product Code: EMA

3. Predicate Devices:

Product	Applicant	510(k) No.	Code No	Predicate	Decision Date
G-CEM LinkForce	GC America Inc.	K153231	EMA	Primary	07/06/2016
G-CEM LINKACE (GAM-200)	GC America Inc.	K120243	EMA	Reference	06/27/2012

4. Description of Device:

G-CEM ONE is a dual-cured self-adhesive resin cement with a tooth primer, G-CEM ONE ADHESIVE ENHANCING PRIMER. The mixed cement hardens 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. Using the primer on the prepared tooth, surface modification and cement polymerization are promoted and hardened along with the cement. The cement syringe consists of Paste A and B, which are filled in a one-body/two chamber syringe. Both pastes are auto-mixed with a mixing tip and applied directly to restorations or 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.

6. Package:
   1. Entrance Kit
      G-CEM ONE syringe (4.6 g / 2.7 mL) (1), G-CEM Automix Tip Regular (8), G-CEM Automix Tip for endo with Extension Tip (2), G-CEM ONE ADHESIVE ENHANCING PRIMER (1),
   2. Twin Refill
      G-CEM ONE syringe (4.6 g / 2.7 mL) (2), G-CEM Automix Tip Regular (15), G-CEM Automix Tip for endo with Extension Tip (5)
   3. Single Refill
      G-CEM ONE syringe (4.6 g / 2.7 mL) (1), G-CEM Automix Tip Regular (8), G-CEM Automix Tip for endo with Extension Tip (2)
   4. G-CEM ONE ADHESIVE ENHANCING PRIMER
      G-CEM ONE ADHESIVE ENHANCING PRIMER (1)

7. Shades available:
   A2, AO3, Translucent, BO1, White opaque

8. Shelf Life and Storage Conditions:
   - Shelf Life 2 years
   - Recommended for optimal performance, store at temperature of 4-25°C (39.2-77.0°F) away from heat, moisture and direct sunlight.

9. Performance Bench Tests:
   It is confirmed that the device conforms to the required specifications of ISO 4049: 2019 Dentistry - Polymer-based restorative materials and Company Specification: 1AB-1500-3-10666.

   Performance testing includes:

G-CEM ONE

	Property	Test method	Requirement
1	Film thickness	ISO 4049: 2019 5.2.2 Film thickness of luting materials	No more than 50 µm.
2	Working time	ISO 4049: 2019 5.2.4 Working time, Class 1 and 3 luting materials	No detectable change in the homogeneity.
3	Setting time	ISO 4049: 2019 5.2.6 Setting time, Class 3 materials	Not more than 10 min.
4	Flexural strength	ISO 4049: 2019 5.2.9 Flexural strength	Equal to or greater than 50 MPa.
5	Water sorption	ISO 4049: 2019 5.2.10 Water sorption and solubility	40 µg/mm^3 or less.
6	Solubility	ISO 4049: 2019 5.2.10 Water sorption and solubility	7.5 µg/mm^3 or less.
7	Radiopacity	ISO 4049: 2019 5.5 Radiopacity	Equal to or greater than the radiopacity of the same thickness of aluminum.

G-CEM ONE ADHESIVE ENHANCING PRIMER

	Property	Test method	Requirement
1	Appearance	Company Specification 1AB-1500-3-10666 - Visual inspection	Should be homogenous and free from foreign matters
2	Coat ability	Company Specification 1AB-1500-3-10666 - Apply a primer thinly on a glass plate using an applicator.	Form uniform film without unevenness
3	Color tone	Company Specification 1AB-1500-3-10666 - Visual inspection	It must be light blue transparent liquid.
4	Refractive index	Company Specification 1AB-1500-3-10666 - Refraction analysis	1.3960-1.3990

10. Non-Clinical Performance Testing:
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.

G-CEM ONE is a dual-cured self-adhesive resin cement with a tooth primer "G-CEM ONE ADHESIVE ENHANCING PRIMER" and does come in contact with body tissues (tooth – enamel, dentin) for more than 24 hours.

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

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

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

Irritation (PRIMARY ORAL (BUCCAL) IRRITATION TEST)
Based on the criteria of the protocol of ISO 10993-10

11. Clinical Performance Testing
No clinical testing has been performed on this device.

12. Comparison of Technology:
The specifications that are important to determine substantial equivalency of a dental adhesive system are bond strengths associated to tooth structure (enamel and dentin) and other substrates. It is also important to evaluate the equivalence of sealing property of dentin tubules.

The bond strength of the applicant device to dentin is equivalent to that of the reference predicate device.

The curing mechanism of the applicant device and predicate device are substantially equivalent in principle. Therefore, the applicant device and predicate device are the same in function, and similar in composition and intended use. This supports that the compatibility of the applicant device is substantially equivalent to the predicate devices.

All the components of the applicant device, G-CEM ONE and G-CEM ONE ADHESIVE ENHANCING PRIMER, have already been used in the predicate devices. The bonding mechanism of the predicate device is applying it to tooth structure, then bonding chemically and mechanically by polymerization of uncured methacrylate ester monomers. Therefore, the subject device has been shown to be substantially equivalent to the predicate device.

The following differences may be noted between G-CEM ONE and the predicate device.

- The applicant device also has a primer which allows it to have additional indications, similar to that of the primary predicate device.
- The applicant device is a self-adhesive resin cement, and unlike the G-CEM LinkForce of an adhesive resin cement, it can be bonded to various materials without a primer.

Table 5.3. Comparison of applicant and predicate

	Applicant Device	Primary Device	Reference Device
Trade name	G-CEM ONE	G-CEM LinkForce K153231	G-CEM LINKACE (GAM-200) K120243
Manufacturer	GC Corporation	GC Corporation	GC Corporation
Product category	Self-adhesive resin cement	Adhesive resin cement	Self-adhesive resin cement
Paste/Paste ratio	Paste A / Paste B = 1.3 / 1.0 (w/w)	Paste A / Paste B = 1.0 / 1.0 (w/w)	Paste A / Paste B = 1.3 / 1.0 (w/w)
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.	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. Permanent cementation of crowns and bridges on implant abutments.	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.
Product description	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.	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.	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.
Instruction for use	1. Tooth preparation 2. Application of G-CEM ONE ADHESIVE ENHANCING PRIMER (Optional) 3. Restoration preparation 4. Dispensing 5. Cementation 6. Excess cement removal 7. Final set 8. Final polishing	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	1. Tooth preparation 2. Restoration preparation 3. Dispensing 4. Cementation 5. Excess cement removal 6. Final set 7. Final polishing
Light curing specification	Light cure using a light curing unit. 10 sec. (High Power LED Light) (>1200mW/cm2) 20 sec. (Halogen/LED) (700 mW/cm2)	Light cure using a light curing unit. 10 sec. (High Power LED Light) (>1200mW/cm2) 20 sec. (Halogen/LED) (700 mW/cm2)	Light cure using a light curing unit. 10 sec. (High Power LED Light) (>1200mW/cm2) 20 sec. (Halogen/LED) (700 mW/cm2)

Table 5.1 (Continued)

	Applicant Device	Primary Device	Reference Device
Trade name	G-CEM ONE	G-CEM LinkForce K153231	G-CEM LINKACE (G-CEM LINKACE (GAM-200)) K120243
Manufacturer	GC Corporation	GC Corporation	GC Corporation
Comparison of Technology	Methacrylates contained in Paste A polymerize by polymerization initiators contained in Paste A and Paste B. In addition, they also polymerize by light irradiation with photo polymerization initiators contained in Paste A. Furthermore, using G-CEM ONE ADHESIVE ENHANCING PRIMER for the cavity and abutment tooth, surface modification and cement polymerization are promoted and hardened with the cement. Methacrylates contained in this material are very hydrophobic and set material is stable. Therefore, the ingredients in the cured material are difficult to elute in water.	Methacrylates contained in Paste A polymerize by polymerization initiators contained in Paste A and Paste B. In addition, they also polymerize by light irradiation thanks to photo polymerization initiators contained in Paste A. Furthermore, using the mixture of G-Premio BOND and G-Premio BOND DCA for the cavity and abutment tooth, surface modification and cement polymerization are promoted and hardened with the cement. Methacrylates contained in this material are very hydrophobic and set material is stable. Therefore, the ingredients in the cured material are difficult to elute in water.	Methacrylates contained in Paste A polymerize by polymerization initiators contained in Paste A and Paste B. In addition, they also polymerize by light irradiation thanks to photo polymerization initiators contained in Paste A. Methacrylates contained in this material are very hydrophobic and set material is stable. Therefore, the ingredients in the cured material are difficult to elute in water.

13. Conclusion

Based on similarities in intended use, mode of action, chemical composition, and performance testing, G-CEM ONE is substantially equivalent to the predicate device.