July 11, 2019

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

Re: K182854
Trade/Device Name: GC FujiCEM 2 (Improved)
Regulation Number: 21 CFR 872.3275
Regulation Name: Dental Cement
Regulatory Class: Class II
Product Code: EMA
Dated: April 12, 2019
Received: April 16, 2019

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 Nandkumar, Ph.D.
Acting Assistant 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

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)*

K182854

Device Name

GC FujiCEM 2 (Improved)

Indications for Use *(Describe)*

- Cementation of metal-based inlays, onlays, crowns and bridges
- Cementation of resin inlays, onlays, crowns and bridges
- Cementation of all ceramic inlays
- Cementation of high strength (e.g. zirconia based, lithium disilicate) ceramic onlays, crowns and bridges
- Cementation of metal, ceramic and fiber posts

Type of Use *(Select one or both, as applicable)*

[X] Prescription Use (Part 21 CFR 801 Subpart D) [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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1. Submitter Information: K182854

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Date Prepared: July 8, 2019

2. Device Name:

Proprietary Name: GC FujiCEM 2 (Improved)
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
GC FujiCEM	GC America Inc.	K001730	EMA	Primary	07/17/2000
GC Fuji Direct	GC America Inc.	K172382	EMA	Reference	04/02/2018
GC G-CEM Automix	GC America Inc.	K073283	EMA	Reference	02/20/2008

4. Description of Device:

GC FujiCEM 2 (Improved) is a resin modified glass ionomer luting cement. The device is composed of the two pastes, Paste A and Paste B, packaged in an automix dual barrel syringe.

GC FujiCEM 2 (Improved) Package:

- Single Pack Automix
  - Syringe (9.2 g / 5 mL) QTY: 1
  - GC Mixing Tip – QTY: 15
- Triple Pack Handmix
  - Syringe (9.2 g / 5 mL) QTY: 3
  - Mixing Pad– QTY: 1
- Triple Pack Automix
  - Syringe (9.2 g / 5 mL) QTY: 3
  - GC Mixing Tip – QTY: 45

Shades available:
Yellow, Brown

Shelf Life and Storage Conditions:

- Shelf Life 2 years
- Recommended for optimal performance, store in a cool and dark place. 4-25°C (39 – 77°F)

5. Indications for Use Statement:
   - Cementation of metal-based inlays, onlays, crowns and bridges
   - Cementation of resin inlays, onlays, crowns and bridges
   - Cementation of all ceramic inlays
   - Cementation of high strength (e.g. zirconia based, lithium disilicate) ceramic onlays, crowns and bridges
   - Cementation of metal, ceramic and fiber posts

6. Non-Clinical Performance Testing:

Biocompatibility: 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.

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 (Intracutaneous Injection Test)
Based on the criteria of the protocol of ISO 10993-10

GC FujiCEM 2 (Improved) is a resin modified glass ionomer luting cement and does come in contact with body tissues (tooth – enamel, dentin) for more than 24 hours.

In conclusion, biocompatibility of GC FujiCEM 2 (Improved) is acceptable device from the biological evaluation result.

Performance Bench Tests: It is confirmed that the device conforms to the required specifications of ISO 9917-2: 2017 (Dentistry - Water-based cements -Part2: Resin-modified cements) and company standard is suitable for its intended use. Performance testing includes:

Property	Requirements
Appearance	No visible sign of extraneous matter Free of any gelation
Working time	The indenter shall make a complete circular indentation.
Setting time	The indenter shall fail to make a complete circular indentation.
Flexural strength	More than 25 MPa
Radiopacity	More than equivalent thickness of aluminum

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

8. Substantial equivalence:
The applicant device complies with all the requirements of ISO 9917-2: 2017 (Dentistry - Water-based cements - Part2: Resin-modified cements).

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.

GC FujiCEM 2 (Improved)	GC FujiCEM
Fluoro-alumino-silicate glass contained in Paste A and Polyacrylic acid contained in Paste B react in the presence of water contained from the paste B. Aluminum ion, Strontium ion and Fluoride ion are released from Fluoro-alumino-silicate glass due to this reaction. Of these ions, Aluminum ion and Strontium ion crosslink the polyacrylic acid and form hydrogel. Fluoride ion doesn't react, it remains inside hydrogel as ion. Methacrylates contained in Paste A polymerize by polymerization initiator contained in Paste B. In addition, they also polymerize by light irradiation thanks to photo polymerization initiator contained in Paste A.	Fluoro-alumino-silicate glass contained in Paste A and Polyacrylic acid contained in Paste B react in the presence of water contained from the paste B. Aluminum ion, Strontium ion and Fluoride ion are released from Fluoro-alumino-silicate glass due to this reaction. Of these ions, Aluminum ion and Strontium ion crosslink the polyacrylic acid and form hydrogel. Fluoride ion doesn't react, it remains inside hydrogel as ion. Methacrylates contained in Paste A polymerize by polymerization initiator contained in Paste B.
This material set by the above two reactions. The set material contains fluoride ion inside as free ion. These ions can be gradually release from the setting material in very small amounts with time.	This material set by the above two reactions. The set material contains fluoride ion inside as free ion. These ions can be gradually release from the setting material in very small amounts with time.

Differences

The following differences may be noted between GC FujiCEM 2 (Improved) and the predicate device.

- The differences are for clarification of Indications for Use.
- The applicant device is hardened through chemical cure and partially hardened through light cure (tack curing). This function is used for removing excess cement. On the other hand, the primary device is hardened through just chemical cure.
- The applicant device is automixed using a static mixing tip, while primary device is hand mixed.
- The applicant device is a resin modified glass ionomer cement for luting while the predicate device, GC Fuji Direct, is resin modified glass ionomer cement for filling.
- The applicant device is resin modified glass ionomer cement while the predicate device, GC G-CEM Automix, is self-adhesive resin cement for luting.

Below is a comparison table between the applicant device, primary device and reference devices, showing the similarities between devices.

	Applicant Device	Primary Device	Reference Device	Reference Device
Trade name	GC FujiCEM 2 (Improved) K182854	GC FujiCEM K001730	GC Fuji Direct K172382	GC G-CEM Automix K073283
Manufacturer	GC Corporation	GC Corporation	GC Corporation	GC Corporation
Product category	Resin modified glass ionomer cement	Resin modified glass ionomer cement	Resin-modified glass ionomer cement	Self-adhesive resin cement
Paste/Paste ratio	Paste A / Paste B = 1.0 / 1.0 (w/w)	Paste A / Paste B = 2.0 / 1.0 (w/w)	Paste A / Paste B = 1.6 / 1.0 w/w)	Paste A / Paste B = 1.3 / 1.0 (w/w)
Indications for Use	1. Cementation of metal-based inlays, onlays, crowns and bridges 2. Cementation of resin inlays, onlays, crowns and bridges 3. Cementation of all ceramic inlays 4. Cementation of high strength (e.g. zirconia based, lithium disilicate) ceramic onlays, crowns and bridges 5. Cementation of metal, ceramic and fiber posts	1. Cementation of metal-based inlays, onlays, crowns and bridges 2. Cementation of resin inlays, onlays, crowns and bridges 3. Cementation of all ceramic inlays 4. Cementation of high strength (zirconia based) all ceramic crowns and bridges 5. Cementation of metal, ceramic and fiber posts	1. Class III and V restorations 2. Restoration of primary teeth 3. Core Build-up 4. Cases where radiopacity is required 5 Base material for Class 1 and Class II cavities using a sandwich laminate technique	GC GAM –100 is intended to be used for cementing all types of ceramic, resin, and metal-based inlays, onlays, crown and bridges, and post.
Product description	The device consists of 2 pastes filled in a dual barrel syringe. Paste A and B are automixed with an automix tip and directly applied to restorations or the prepared cavity.	The device consists of 2 pastes filled in a Paste Pak Cartridge. Paste A and B are dispensed with Paste Pak Dispenser and hand mixed. The mixed cement is applied to restorations or the prepared cavity.	The device consists of 2 pastes filled in cartridges. Paste A and B are automixed with an automix tip and directly applied to the prepared cavity.	The device consists of 2 pastes filled in a one body syringe. Paste A and B are automixed with an automix tip and directly applied to restorations or the prepared cavity.
Instruction for use	1. Tooth preparation 2. Restoration preparation 3. Dispensing 4. Cementation 5. Cleaning up excess cement 6. Finishing restoration and check occlusion.	1. Tooth preparation 2. Restoration preparation 3. Dispensing 4. mixing pastes 5. Cementation 6. Cleaning up excess cement 7. Finishing restoration and check occlusion.	1. Tooth preparation 2. Mix of 2 pastes 3. Application to cavity 4. Finishing	1. Tooth preparation 2. Restoration preparation 3. Dispensing 4. Cementation 5. Cleaning up excess cement 6. Finishing restoration and check occlusion.

Light curing specification	Optionally, tack cure using light for removing excess cement.		Light cure using a light curing unit. 10 sec. (High Power LED Light) (>1200mW/cm2) 20 sec. (Halogen/LED) (700 mW/cm2)	light cure all surfaces/margins for 20 seconds each (Halogen/LED 700mW/cm2).
Technological Characteristics and Mode of action	The device is set by acid-base reaction and polymerization after mixing 2 pastes. Acid-base reaction occurs Fluoro-alumino-silicate glass in Paste A and Polyacrylic acid in Paste B. Polymerization of methacrylate monomers is through chemical cure. It is also partially hardened through light cure (tack cure). This is used for removing excess cement.	The device is set by acid-base reaction and polymerization after mixing 2 pastes. Acid-base reaction occurs Fluoro-alumino-silicate glass in Paste A and Polyacrylic acid in Paste B. Polymerization of methacrylate monomers is through chemical cure.	The device is set by acid-base reaction and polymerization after mixing 2 pastes. Acid-base reaction occurs Fluoroalumino-silicate glass in Paste A and Polyacrylic acid in Paste B. Polymerization of methacrylate monomers is through dual cure	The device is set by polymerization after mixing 2 pastes. Polymerization of methacrylate monomers is through dual cure.
Sizes	Single Pack Automix - Syringe (9.2 g / 5 mL) QTY: 1 - GC Mixing Tip – QTY: 15 Triple Pack Handmix - Syringe (9.2 g / 5 mL) QTY: 3 - Mixing Pad– QTY: 1 Triple Pack Automix - Syringe (9.2 g / 5 mL) QTY: 3 - GC Mixing Tip – QTY: 45	1. GC FujiCEM Refill (Automix compatible) Paste Pak Cartridge (13.3g / 7.2mL) (2) with mixing pad (No.22) 2. GC FujiCEM Automix Paste Pak Cartridge (13.3g / 7.2mL) (2), GC FujiCEM Mixing Tip (44) 3. Paste Pak Dispenser (1)	1 x Paste Pak Cartridge SL (14.9g / 7.2mL) 20 x GC Fuji Mixing Tip SL with intraoral tip 1 x Paste Pak Dispenser II	1. G-CEM Automix syringe 4.8 g (2.7 mL) (2), G-CEM Automix Tip Regular (20) 2. G-CEM Automix Tip Regular (20) 3. G-CEM Automix Tip for endo including extension tip (10)
Shades	Yellow, Brown	Yellow	A1, A2, A3 based on Vita® shades	A2 (Vita® shade), AO3 (opaque), BO1 (opaque) and Translucent
Sterility	This device does not require sterilization.	This device does not require sterilization.	This device does not require sterilization.	This device does not require sterilization

9. Conclusion

Based on similarities in intended use, mode of action, chemical composition, and performance testing, GC FujiCEM 2 (Improved) is substantially equivalent to the predicate device.