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

April 2, 2018

Re: K172382
Trade/Device Name: GC Fuji Direct
Regulation Number: 21 CFR 872.3275
Regulation Name: Dental Cement
Regulatory Class: Class II
Product Code: EMA, EBF
Dated: February 27, 2018
Received: February 28, 2018

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mary S. Runner -S

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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)*
K172382

Device Name
GC Fuji Direct

Indications for Use *(Describe)*
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 I and Class II cavities using a sandwich laminate technique.

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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Section 5 – 510(k) Summary

K172382

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1. Submitter Information:

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Date Prepared: March 26, 2018

2. Device Name:

Proprietary Name: GC Fuji Direct
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 FUJI FILLING LC	GC America Inc.	K051427	EMA	Primary	08/22/2005
GC Fuji II LC Capsule	GC America Inc.	K993973	EMA	Reference	01/11/2000
GC FUJICEM 2	GC America Inc.	K001730	EMA	Reference	07/17/2000
GC Kalore	GC America Inc.	K082434	EBF	Reference	11/14/2008

4. Description of Device:

GC Fuji Direct is a light-cured resin-modified restorative glass ionomer cement. The device consists of two pastes filled in a Paste Pak Cartridge. Paste A and B are dispensed with Paste Pak Dispenser II and hand mixed. Paste A and B can also be automixed by attaching the GC Fuji Direct Mixing Tip to the Paste Pak Dispenser II and applied directly to the prepared cavity. The bioactive material sets by acid-base reaction of fluoroalumino-silicate glass and Polyacrylic acid, and polymerization of methacrylate monomers.

GC Fuji Direct Package:

- Paste Pak Cartridge (14.9 g / 7.2 mL) (1)
- GC Fuji Direct Mixing Tip (20)
- Paste Pak Dispenser II (1)

Shades available:

A1, A2, A3

Shelf Life and Storage Conditions:

- Shelf Life 2 years
- Recommended for optimal performance, store in a cool and dark place. 4-25°C (39.2 - 77.0°F)

5. Indications for Use:
    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

6. Performance Bench Tests:
It is confirmed that the device conforms to the required specifications of ISO 9917-2:2010.

7. 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.

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 Fuji Direct is a light-cured resin-modified restorative glass ionomer cement and does come in contact with body tissues (tooth – enamel, dentin) for more than 24 hours.

In conclusion, biocompatibility of GC Fuji Direct is acceptable device from the biological evaluation result.

It is confirmed that the device conforms to the required specifications of ISO 9917-2: 2010 (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
Shade and color stability	*Shade: Shall match with the manufacture's nominated shade guide *Color stability: No significant change from the reference specimen

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

Table 5.1

	Applicant device	Primary Device	Reference Device	Reference Device	Reference Device
Trade name	GC Fuji Direct K172382	GC FUJI FILLING LC K051427	GC Fuji II LC Capsule K993973	GC FujiCEM 2 K001730	GC Kalore K082434
Manufacturer	GC Corporation	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	Radiopaque reinforced glass ionomer Luting cement	Light-cured composite restorative
Paste/Paste ratio Or Powder/Liquid ratio	Paste A / Paste B = 1.6 / 1.0 (w/w)	Paste A / Paste B = 3.3 / 1.0 (w/w)	Powder / Liquid = 3.3 / 1.0 (w/w)	Paste A / Paste B = 2.0 / 1.0 (w/w)	- (1-paste)
Indications for Use	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	1. Class III and V restorations, particularly for cervical erosions and root surface caries 2. Restoration of primary teeth 3. Core build up 4. Cases where radiopacity is required 5. As a base or a liner	1. Class III and V restoration; particularly areas of cervical erosion, abfraction lesions and root surface caries 2. Restoration of primary teeth 3. As a base of liner 4. Core build-ups/block-outs (particularly of vital teeth) 5. Cases in which a radiopaque restoration is required	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. Direct restorative for Class III, IV, V cavities. 2. Direct restorative for wedge-shaped defects and root surface cavities. 3. Direct restorative for veneers and diastema closure. 4. Direct restorative for Class I and II cavities.
Product description	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 bioactive material sets by acid-base reaction of fluoroalumino-silicate glass and Polyacrylic acid, and polymerization of methacrylate monomers.	The device consists of 2 pastes filled in cartridges. Paste A and B are mixed and directly applied to the prepared cavity. The material sets by acid-base reaction of fluoroalumino-silicate glass and Polyacrylic acid, and polymerization of methacrylate monomers.	The device consists of powder and liquid filled in a capsule. Powder & liquid are mixed with electric capsule mixers. The mixed material is directly applied to a prepared cavity using a capsule applier. The material sets by acid-base reaction of fluoroalumino-silicate glass and Polyacrylic acid, and polymerization of methacrylate monomers.	The device consists of 2 pastes filled in a Paste Pak Cartridge. The material is dispensed with GC Paste Pak Dispenser and hand-mixed. Optionally GC FujiCEM Mixing Tip is available for automixing while pastes dispensation.	The device is a light-cured micro-filled radiopaque composite resin for the restoration of both anterior and posterior teeth. The device consists of two delivery systems, Unitip and Syringes. The system is available in a variety of shades.

Table 5.1 (Continued)

Instruction for use	1. Tooth preparation 2. Mix of 2 pastes 3. Application to cavity 4. Finishing	1. Tooth preparation 2. Mix of 2 pastes 3. Application to cavity 4. Finishing	1. Tooth preparation 2. Mix of powder and liquid 3. Application to cavity 4. Finishing	1. Tooth preparation 2. Restoration preparation 3. Mix of 2 pastes 4. Cementation	1. Tooth Preparation 2. Bonding Treatment 3. Placement of GC KALORE 4. Contouring before Light Curing 6. Light Curing 7. Finishing and 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 the material with a visible light curing device. In the case of G-Light, light-cure for 20 seconds.	Light-cure for 20 seconds using a suitable visible light curing device (470nm wavelength)		Light cure GC KALORE using a light curing unit. In the case of High power LED (more than 1200mW/cm2) light-cure for 10 seconds. In the case of Halogen / LED (700mW/cm2) light-cure for 20 seconds.
Technological Characteristics and Mode of action	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 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 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 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 consists of several kinds of monomers to be polymerized, and filler elements. The device is set by polymerization. Polymerization of methacrylate monomers is through light cure.

9. Substantial equivalence:

The applicant device complies with all the requirements of ISO 9917-2: 2010 (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.

10. Differences

The following differences may be noted between GC Fuji Direct and the predicate device.

- There are slight differences in indications for use, however, differences are verbiage. The same applies to reference device, GC Fuji II LC Capsule.
- The applicant device is automixed with an automix tip while the predicate device is hand mixed.

11. Conclusion

Based on similarities in intended use, mode of action, chemical composition, and performance testing, GC Fuji Direct is substantially equivalent to the predicate device.