July 2, 2020

GC America Inc.
Mark Heiss
Director, Regulatory Affairs
3737 W. 127th Street
Alsip, Illinois 60780-3

Re: K193484
Trade/Device Name: GC Fuji Triage EP
Regulation Number: 21 CFR 872.3275
Regulation Name: Dental Cement
Regulatory Class: Class II
Product Code: EMA
Dated: June 2, 2020
Received: June 5, 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

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)*

Device Name
GC Fuji Triage EP

Indications for Use *(Describe)*

- Pit & Fissure Sealant and Root Surface Sealant
- Hypersensitivity due to abrasion and early non-cavitated lesions
- Protection immature enamel
- Temporary filling including endodontic access

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.

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

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510(k) Summary

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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: June 30, 2020

1. Device Name:

Proprietary Name: GC Fuji Triage EP
Classification Name: Conventional Glass Ionomer Cement
Device Classification: Class II, 872.3275
Product Code: EMA

2. Predicate Devices:

Product	Applicant	510(k) No.	Code No	Predicate	Decision Date
GC Fuji Triage	GC America Inc.	K013198	EMA	Primary	10/29/2001
MI VARNISH	GC America Inc.	K102808	LBH	Reference	12/22/2010

3. Description of Device:

GC Fuji Triage EP is a bioactive glass ionomer for temporary restorative material. The device consists of powder and liquid filled in a capsule and is mixed with a capsule mixer. Then, the mixture is applied directly to a cavity with a capsule applier. As an additional improvement, a proprietary elongation tip can be attached to the capsule nozzle which enables access to small or deep cavities. GC Fuji Triage EP contains CPP-ACP (casein phosphopeptide – amorphous calcium phosphate) in the formulation. CPP-ACP was added to moderate the strength of cement for its use and provide a source of Ca+ and HPO4-2. CPP-ACP was chosen as the additive for regulating the strength because it does not interfere with the setting reaction of the material.

GC Fuji Triage EP Package:
Capsule (Powder 0.30g/Liquid 0.15g) - QTY: 50

Shades available: Pink, White

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)

4. Performance Bench Tests:

It is confirmed that the device conforms to the required specifications of ISO 9917-1:2007.

5. 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.

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 Triage EP is a bioactive glass ionomer for temporary restorative and does come in contact with body tissues (tooth – enamel, dentin) for more than 30 days

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

It is confirmed that the device conforms to the required specifications of ISO 9917-1: 2007 Dentistry – Water-based cements – Part 1: Powder/liquid acid-base cements and company standard is suitable for its intended use. Performance testing includes:

	Property	**Requirements**
1	Net setting time	1.5 to 6 min
2	Compressive strength	More than 100 MPa
3	Acid erosion	Less than 0.17 mm
4	Optical properties (opacity)	0.35 to 0.90
5	Optical properties (color)	Match the nominated shade guide
6	Acid-soluble lead content	Less than 100mg/kg
7	Radiopacity	More than equivalent thickness of aluminum

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

7. Comparison of Technology:
The hardening mechanism of GC Fuji Triage EP and GC Fuji Triage are substantially equivalent in principle. Thus, the applicant device and the 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.

The following differences may be noted between GC Fuji Triage EP and the predicate devices:

- GC Fuji Triage EP contains CPP-ACP (casein phosphopeptide – amorphous calcium phosphate) in the formulation.
- GC Fuji Triage EP includes the elongation tip.
- The applicant device, Fuji Triage EP, is a glass ionomer cement while MI VARNISH is a topical fluoride varnish.

8. Conclusion
The applicant device, GC Fuji Triage EP, is substantially equivalent in qualitative features to the comparative device, FUJI Triage.

	Applicant Device	Primary Device	Reference Device
Trade name	GC Fuji Triage EP	FUJI Triage K013198	MI VARNISH K102808
Manufacturer	GC Corporation	GC Corporation	GC Corporation
Product category	Restorative glass ionomer cement	Restorative glass ionomer cement	Topical fluoride varnish
Powder/Liquid ratio	Powder 0.30g/Liquid 0.15g	Powder 0.30g/Liquid 0.15g	Not applicable
Indications for Use	1. Pit & Fissure Sealant and Root Surface Sealant 2. Hypersensitivity due to abrasion and early non-cavitated lesions 3. Protection immature enamel 4. Temporary filling including endodontic access	1. Pit and fissure sealant. 2. Treatment of early non-cavitated lesions; such as tooth brush abrasion and root surface sensitivity 3. Intermediate restorative material 4. Temporary filling of endodontic access.	Treatment of hypersensitive teeth.
Product description	The Device consists of powder and liquid and filled in a capsule. The mixed cement sets by acid-base reaction of fluoro-alumino-silicate glass and polyacrylic acid.	The device consists of powder and liquid and filled in a capsule. The mixed cement sets by acid-base reaction of fluoro-alumino-silicate glass and polyacrylic acid.	The device is a 5% sodium fluoride varnish that a desensitizing action when applied to tooth surfaces. The application leaves a film of varnish on tooth surfaces.
Technological Characteristics and Mode of action	GC Fuji Triage EP contains CPP-ACP (casein phosphopeptide – amorphous calcium phosphate). CPP-ACP was added to moderate the strength of cement for the use as more temporary or provisional restoration material. CPP-ACP was chosen as the additive for regulating the strength because it does not inhibit the setting reaction of the material while can tone down the physical strength. 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. This material set by the above reaction. 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.	GC Fuji Triage Capsule is radiopaque glass ionomer protection and temporary restorative material in capsules consisting of powder and liquid. The powder is Fluoro-alumino-silicate glass and liquid is Polyacrylic acid solution. They are mixed with an electrical capsule mixer and applied directly to a cavity with a capsule applier. 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. This material set by the above reaction. 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.	MI Varnish is a paste formula delivered in unit dose package. The laminating film lid is peeled off and the paste is applied on the tooth surface with a disposable brush. The device is a 5% sodium fluoride varnish and also contains CPP-ACP (casein phosphopeptide – amorphous calcium phosphate) in the formula. When the device is applied on the tooth surface, a thin film of varnish is left on the tooth surface by evaporation of ethanol on tooth. The film is composed by polyvinyl acetate as film former and hydrogenated rosin as adhesives. The film works for desensitizing of the tooth surface.