November 22, 2019

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

Re: K192260
Trade/Device Name: everX Flow
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: Class II
Product Code: EBF
Dated: August 20, 2019
Received: August 21, 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 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)*
K192260

Device Name
everX Flow

Indications for Use *(Describe)*

everX Flow is a reinforcing dentin replacement material suitable for:
1. All direct composite restorations including large posterior cavities.
2. Deep cavities and endo-treated teeth.
3. Cavities with missing cusps or after amalgam removal and cavities where inlays and onlays would also be recommended.
4. Core build-up

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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW. ***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer Paperwork
Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

PSC Publishing Services (301) 443-6740 EF

1

510(k) Summary – K192260

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: October 28, 2019

2. Device Name:

Proprietary Name: everX Flow
Classification Name: Tooth shade resin material
Device Classification: Class II, 872.3690
Product Code: EBF

3. Predicate Devices:

Product	Applicant	510(k) No.	Code No	Predicate	Decision Date
everX Posterior	GC America Inc.	K153127	EBF	Primary	05/20/2016
Gradia Core	GC America Inc.	K082171	EBF	Reference	10/30/2008
G-aenial Flo X	GC America Inc.	K133182	EBF	Reference	4/9/2014

4. Description of Device:

everX Flow is a light cured, short-fiber-reinforced composite for dentin replacement for the restoration of posterior and anterior teeth. EverX Flow is filled in a syringe. The material is available in two shades, Bulk shade and Dentin shade.

5. Indications for Use:

- everX Flow is a reinforcing dentin replacement material suitable for:
  All direct composite restorations including large posterior cavities.
- Deep cavities and endo-treated teeth.
- Cavities with missing cusps or after amalgam removal and cavities where inlays and onlays would also be recommended.
- Core build-up

6. Packaging

everX Flo Package:

- Syringe (3.7 g / 2 mL) QTY: 1
- Dispensing Tip III QTY: 20
- Light protective cap QTY: 1

7. Shades

Shades available: Bulk Shade, Dentin Shade

8. Shelf Life and Storage Conditions:
   - Shelf Life 3 years
   - Recommended for optimal performance, store in a cool and dark place (4-25°C / 39.2-77.0°F) away from high temperatures or direct sunlight.

9. Performance Bench Tests

   It is confirmed that the device conforms to the required specifications and is suitable for its intended use. Performance testing includes:
   - Sensitivity to ambient light
   - Depth of cure
   - Flexural strength
   - Water sorption
   - Solubility
   - Color stability after irradiation and water sorption
   - Radiopacity

   The applicant device complies with all the requirements of ISO 4049: 2009 (Dentistry - Polymer-based restorative materials) (see table below).

	Property	Requirements
1	Sensitivity to ambient light	Remain physically homogeneous
2	Depth of cure	Opaque shade: > 1.0 mm Other shade: > 1.5 mm
3	Flexural strength	> 80 MPa
4	Water sorption	< 40 $\mu g/mm^3$
5	Solubility	< 7.5 $\mu g/mm^3$
6	Color stability after irradiation and water sorption	No more than slight change in color
7	Radiopacity	Greater than the same thickness of aluminum

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.
    Based on the criteria of the protocol and the ISO 10993-5 guidelines, the test article meets the requirements of the test and is not considered to have a cytotoxic effect.

11. Clinical Performance Testing

    No clinical testing has been performed on this device.

12. Comparison of Technology

    The main difference between the applicant device and primary predicate device is the flow. The indications for use were similar as well. The formula was modified without issue associated with safety and efficacy. In addition, biocompatibility studies were successfully completed. Mechanism for curing and polymerization did not change. Also, depth of cure was similar.

	Applicant device	Primary Predicate Device	Reference Predicate Device	Reference Device
Product category	**Tooth shade resin material, Class II**	**Tooth shade resin material, Class II**	**Tooth shade resin material, Class II**	Tooth shade resin material, Class II
Trade name	**everX Flow**	**everX Posterior**	**Gradia Core**	G-AENIAL FLO X (HTFX-222)
510(k)	**Pending**	**K153127**	**K082171**	**K133182**
Manufacturer	**GC Corporation**	**GC Corporation**	**GC Corporation**	GC Corporation
Indications for use	everX Flow is a reinforcing dentin replacement material suitable for: 1. All direct composite restorations including large posterior cavities. 2. Deep cavities and endo-treated teeth. 3. Cavities with missing cusps or after amalgam removal and cavities where inlays and onlays would also be recommended. 4. Core build-up	everX Posterior is suitable for use as the reinforcing material for direct composite restorations, especially in large posterior cavities, for example: 1. Cavities including 3 surfaces or more. 2. Cavities with missing cusps. 3. Deep cavities (including class I, II and endodontically treated teeth). 4. Cavities after amalgam replacement. 5. Cavities where onlays & inlays would also be indicated.	GRADIA CORE is intended to be used for restoration, core build-up and post cementation.	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 small Class II, III, IV, I and V cavities
Product description	everX Flow is a light cured, short-fiber-reinforced composite for dentin replacement for the restoration of posterior and anterior teeth. EverX Flow is filled in a syringe. The material is available in two shades, Bulk shade and Dentin shade.	everX Posterior is a fiber-reinforced composite resin filled in a unitip. The device is a universal type. The material is available in one universal shade. The device is suitable for use as the reinforcing material for direct composite restorations, especially in large posterior cavities.	GRADIA CORE consists of the two articles, GRADIA CORE cartridge and GRADIA CORE self-etching bond. GRADIA CORE cartridge is a two-paste (base and catalyst) type, dual-cured composite resin filled in double syringe to provide auto-mixing system. GRADIA CORE cartridge paste comprises four shades, Universal, Dentin, White and Blue. GRADIA CORE self-etching bond is a two-liquid (liquid A and liquid B), dual-cured self-etching bonding agent.	G-AENIAL FLO X (HTFX-222) is a light cured nano-filled radiopaque composite resin filled in a syringe. The device is used for the restorations of both anterior and posterior teeth
Technological Characteristics and Mode of action	The curing mechanism is polymerization of uncured methacrylate ester monomers. This reaction is caused by photo initiator system.	The curing mechanism of the predicate is polymerization of uncured methacrylate ester monomers. This reaction is caused by photo initiator system.	The curing mechanism of the predicate is polymerization of uncured methacrylate ester monomers. This reaction is caused by photo initiator system and is assisted by chemical curing.	The curing mechanism of the predicate devices is polymerization of uncured methacrylate ester monomers. This reaction is caused by photo initiator system.

13. Conclusion

Based upon similarities in technology and indications for use, as well as results of non-clinical performance testing, we believe that everX Flow is substantially equivalent to the predicate devices.