DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 20, 2016

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

Re: K153127
Trade/Device Name: everX Posterior
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: II
Product Code: EBF
Dated: April 21, 2016
Received: April 22, 2016

Dear Dr. 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section 4 – Indications for Use Statement

Indications for Use

510(k) Number: K153127

Device Name: everX Posterior

Indications for Use:

everX Posterior is indicated for use as a fiber reinforced composite for the restoration of prepared carious teeth, including large posterior cavities with loss of dentin.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Section 5 – 510(k) Summary

GC AMERICA INC.
3737 W 127th STREET
ALSIP, ILLINOIS 60803
TEL (708) 597-0900
FAX (708) 926-9100
www.gcamerica.com

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) 926-9100

Date Prepared: April 21, 2016

2. Device Name:

510(k) Number: K153127
Proprietary Name: everX Posterior
Classification Name: Tooth shade resin material
Device Classification: Class II, 872.3690
Product Code: EBF

3. Predicate Devices:

	Product	Applicant	Submission	Procode
Primary	Build-It Total Core	Sybron Dental Specialties, Inc.	K102703	EBF
Reference	G-aenial Sculpt (MFP-051)	GC America Inc.	K123631	EBF

4. Description of Device:

everX Posterior is a light-cured, fiber-reinforced, universal type composite resin packaged in a unitip and available in one universal shade.

5. Indications for Use:

everX Posterior is indicated for use as a fiber reinforced composite for the restoration of prepared carious teeth, including large posterior cavities with loss of dentin.

6. Technological characteristics:

The applicant device is composed of randomly oriented short E-glass and inorganic particulate fillers in combination with a semi-interpenetrating polymer network matrix that consists of bisphenol A glysidyl methacrylate, triethyleneglycol dimethacrylate and polymethylmethacrylate. The glass fibers are pre-impregnated into the composite resin and are 0.8 mm average length.

	Applicant device	Predicate Device	Reference Device
Trade name	everX Posterior	Build-It Total Core	G-ænial Sculpt (MFP-051)
Manufacturer	GC Corporation	Sybron Dental Specialties	GC Corporation
Indications for Use	everX Posterior is indicated for use as a fiber reinforced composite for the restoration of prepared carious teeth, including large posterior cavities with loss of dentin.	Build-it Total Core is indicated for use as 1. Core build up material on vital and non-vital teeth 2. Sealing root canal openings, 3. Cavity floor liner, 4. Post cementation, 5. Restorative material 6. Dentin replacement material.	1. Direct restorative for class I, II, III, IV, V cavities. 2. Direct restorative for wedge-shaped defects and root surface cavities. 3. Direct restorative for veneers and diastema closure.
Product description	everX Posterior is a fiber-reinforced, universal shade composite resin paste filled in a unitip suitable as a reinforcing material for direct composite restorations, especially in large posterior cavities. Physical properties are within the acceptable range for flexural strength, depth of cure, water sorption, solubility in accordance with ISO 4049:2009 Dentistry – Polymer based restorative materials	Build-it Total Core is a two component, catalyst and base, fiber reinforced, self-adhesive composite that contains fluoride, and is available in esthetic and contrast shades Physical properties tested include flexural strength, compressive strength, water solubility, water absorption	G-aenial Sculpt is a light cured nano-filled radiopaque composite resin filled in a syringe and unitip and available in several shades. The device is used for the restorations of both anterior and posterior teeth. Physical properties tested In accordance with ISO 4049:2009 Dentistry – Polymer based restorative materials
Mode of action	The paste material with glass fibers contains a photo initiator to allow for polymerization through light curing resulting in a solid material for dental restorations.	The two component paste material uses dual cure to become a solid material for dental restorations	G-aenial Sculpt is a paste composite reinforced by a dispersion of filler particles bonded to the resin matrix with a photo initiator to allow for curing/conversion. The end result is a conversion from a paste to a solid material for dental restorations.

7. Non clinical performance testing

Bench testing was performed in accordance with ISO 4049:2009 Dentistry – Polymer based restorative materials, and the testing results indicate that the device conforms to the required specifications for sensitivity to ambient light, depth of cure, flexural strength, water sorption, solubility, and color stability after irradiation and water sorption and is therefore suitable for the intended use.

8. Biocompatibility

Biocompatibility assessment was based upon ISO 10993-1 and testing included cytotoxicity in accordance with ISO 10993-5, and sensitization and irritation in accordance with ISO 10993-10.

9. Substantial equivalence:

everX Posterior is similar to the primary predicate (K102703) Build-It Total Core in that both are fiber

reinforced composite material used for dental restorations; both devices make use of pre-impregnated glass fibers to provide support to the composite mix for their intended use: both devices are indicated for use in large cavities with loss of dentin including posterior teeth, tooth core structure replacement or build up. The predicate device is not indicated for use as a root canal sealer and cavity liner because it is not self-adhesive meaning like the predicate K102703. A technologic difference between the applicant device and primary predicate device is that the applicant device is a light cured paste with a photo initiator, while the predicate device K102703 is a dual cure, two paste system of catalyst and base, and that contains fluoride. In principle, the curing mechanism of the applicant and predicate devices is substantially equivalent in principle as they both undergo polymerization to become a solid material adapted to a cavitation in a tooth to become a dental restoration.

everX Posterior and the reference predicate G-aenial Sculpt (K123631) are both light cured composite resins intended to be used as dental restorative materials: the device formulations are identical for all components, except that the applicant device also includes glass fibers and polymethylmethacrylate. everX Posterior is available only in universal shade whereas both of the predicates are available in a range of shades.

All three devices have been tested for physical properties including flexural strength, water sorption, depth of cure. The results of testing the physical properties of the applicant device in accordance with the FDA recognized standard for polymer based restorative materials used in dentistry, demonstrate that the applicant device is similar to the predicate devices in function and intended use.

10. Conclusion

Given the similarities in intended use, mode of action, and chemical composition, and in consideration of the results of non-clinical performance testing and biocompatibility testing, everX Posterior is substantially equivalent to the predicate and reference devices.