DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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April 20, 2015

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

Re: K143140
Trade/Device Name: G-Premio BOND
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin, tooth bonding agent
Regulatory Class: II
Product Code: KLE
Dated: December 15, 2014
Received: January 20, 2015

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" (21CFR 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,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
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Erin I. Keith, M.S.
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Center for Devices and
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Enclosure

Section 4 – Indications for Use Statement

Indications for Use

510(k) Number (if known): K143140

Device Name: G-Premio BOND

Indications for Use:

1. Bonding of light cured composites and acid modified composites (compomers) to tooth structure.
2. Bonding of dual cured luting and core build up composites to tooth structure as long as these materials are light cured.
3. Intraoral repairs of porcelain fused to metal crowns and composite veneer crowns with metal backing.
4. Intraoral repairs of all ceramic crowns (except zirconia and alumina), hybrid resin jacket crowns, CAD/CAM hybrid resin crowns and composites.
5. Intraoral repairs of porcelain fused to zirconia crowns, porcelain fused to alumina crowns and full zirconia crowns.
6. Treatment of hypersensitive teeth.

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)

1. Submitter Information:

GC America Inc.
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Alsip, IL 60803

Contact Person: Mark Heiss, D.D.S.
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Date Prepared: October 30, 2014

2 Device Name:

510(k) Number: K143140
Proprietary Name: G-Premio BOND
Classification Name: Resin tooth bonding agent
Device Classification: Class II, 872.3200
Product Code: KLE

1. Predicate Devices:

Company	Device	510(k) No.	Date Cleared
GC America Inc.	G-ænial Bond	K082768	2008/10/21

2. Description of Device:

G-Premio BOND is a one component, light-cured bonding agent available in a 5 mL liquid bottle or unit dose.

3. Indications for Use:

a. Bonding of light cured composites and acid modified composites (compomers) to tooth structure.
b. Bonding of dual cured luting and core build up composites to tooth structure as long as these materials are light cured.
c. Intraoral repairs of porcelain fused to metal crowns and composite veneer crowns with metal backing.
d. Intraoral repairs of all ceramic crowns (except zirconia and alumina), hybrid resin jacket crowns, CAD/CAM hybrid resin crowns and composites.
e. Intraoral repairs of porcelain fused to zirconia crowns, porcelain fused to alumina crowns and full zirconia crowns.
f. Treatment of hypersensitive teeth.

4. Technological characteristics:

All the compounds found in the applicant device, G-Premio BOND, have already been used in the predicate devices. The bonding mechanism of the predicate device is applying it to tooth structure, then bonding chemically and mechanically by polymerization of uncured methacrylate ester monomers. The chemical composition of the subject device is such that it can also bond to tooth surfaces (like the predicate) as well as composites, hybrid ceramics, ceramics, and metals.

5. Substantial equivalence:

The subject and predicate devices contain the same compounds, have similar indications, and are both light cured.

	Applicant device	Comparative device
Product category	Resin tooth bonding agent, Class II	Resin tooth bonding agent, Class II
Trade name	G-Premio BOND	G-ænial Bond
Manufacturer	GC Corporation	GC Corporation
Intended use	For bonding light-cured composite resin to tooth structure, hybrid ceramics, composites, ceramics (porcelain, lithium disilicate, zirconia and alumina) and metals (precious and non-precious metals) surfaces. For treatment of hypersensitive teeth.	For bonding light-cured composite resin to tooth structure.
Product description	G-Premio BOND is a one component, light-cured bonding agent available in a 5 mL liquid bottle or unit dose.	G-aenial Bond is a one component, light-cured bonding agent that allows bonding light-cured composite resins to tooth structure.

The applicant device complies with all the requirements of Company specification AB-15-Q-301-631(1) (see table below).

Property		Requirements
1	Appearance	Should be homogenous and free from foreign matters
2	Curing property	Should be cured and formed film
3	Bond strength to tooth structure	>10MPa for enamel
		>10MPa for dentin
4	Bond strength to metal	>10MPa for precious metal
		>10MPa for non-precious metal
5	Bond strength to ceramic and composite	>10MPa for porcelain
		>10MPa for composite
		>10MPa for zirconia
6	Application characteristics	Should be formed even and homogenous coat.
7	Sealing property of dentin tubules	Should be sealed dentin tubules when observed using SEM

6. Differences

The following differences may be noted between the predicate device and G-Premio BOND.

- G-Premio BOND is available for bonding light-cured composite resin to composites, hybrid ceramics, ceramics and metals surfaces as well as tooth structure.
- G-Premio BOND is available for treatment of hypersensitive teeth.

The specifications that are important to determine substantial equivalency of a dental adhesive system are bond strengths associated to enamel and dentin (tooth structure). The bond strengths as noted above compare the predicate device (G-aenial Bond, K082768) to the subject device. In both enamel and dentin bonding, the results were equivalent.

In addition, bond strength of subject device to other substrates was equivalent to the predicate bond strengths to enamel and dentin. SEM images of sealed bovine dentin tubules also support indications for treatment of hypersensitive teeth.

Therefore, the subject device has been shown to be substantially equivalent to the predicate device.

7. Performance Bench Tests

It is confirmed that the device conforms to the required specifications and is suitable for its intended use. Performance testing includes:

- Appearance
- Curing property
- Application characteristics
- Color
- pH
- Filler loading
- Refraction index

8. Packaging

G-Premio BOND Bottle:

- 5 mL liquid (1), disposable dispensing dish (20), disposable applicator (50)

G-Premio BOND Unit Dose:

- 0.1mL liquid (50), disposable applicator (50)

9. Shelf Life Evaluation and Storage Conditions:

- Shelf Life 2 years
- Recommended for optimal performance, store in a cool and dark place. 1-25°C (33.8 - 77.0°F)

10. Conclusion

Based on similarities in intended use, mode of action, chemical composition, and performance testing, G-Premio Bond is substantially equivalent to the selected predicate (K082768).