October 2, 2020

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

Re: K200682
Trade/Device Name: Bzf-29
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: Class II
Product Code: KLE
Dated: June 30, 2020
Received: July 6, 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

Section 4 – Indication for Use statement

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)* K200682

Device Name
BZF-29

Indications for Use *(Describe)*

BZF-29 is a two component (PRIMER and ADHESIVE), light-cured bonding agent suitable for:

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

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.

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K200682

510(k) Summary

1. Submitter Information:

GC America Inc.
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Alsip, IL 60803

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Phone: (708) 926-3092
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Date Prepared: October 1, 2020

2. Device Name:

Proprietary Name: BZF-29
Classification Name: Resin tooth boding agent
Device Classification: Class II, 872.3200
Product Code: KLE

3. Predicate Devices:

Product	Applicant	510(k) No.	Code No	Predicate	Decision Date
G-Premio BOND	GC America Inc.	K143140	KLE	Primary	04/20/2015

4. Description of Device:

BZF-29 is a two component, light-cured bonding agent to bond light-cured composite resins to tooth structure, composites, hybrid ceramics, ceramics and metal surfaces, and for the treatment of hypersensitive teeth.

5. Indications for Use:

BZF-29 is a two component (PRIMER and ADHESIVE), light-cured bonding agent suitable for:

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

6. Packaging

BZF-29 Bottle Package:

- PRIMER liquid (Bottle / 5 mL) QTY: 1
- ADHESIVE liquid (Bottle / 5 mL) QTY: 1
- Disposable applicator QTY: 100
- Disposable dispensing dish QTY: 20

BZF-29 Unit Dose Package:

- PRIMER liquid (Unit Dose / 0.1 mL) QTY: 50
- ADHESIVE liquid (Unit Dose / 0.1 mL) QTY: 50
- Disposable applicator QTY: 100

7. Shelf Life and Storage Conditions:

- Shelf Life 2 years
- Recommended for optimal performance, store at temperature of 4-25°C (39.2-77.0°F)

8. 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
- Refraction index

The applicant device complies with all the requirements of 1AB-1500- 3-10706 (Company specification) (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	Application characteristics	Should be formed even and homogenous coat.
4	Color	Yellow opaque for PRIMER, Yellow for ADHESIVE
5	pH (only for PRIMER)	1.3 to 1.8
6	Refraction index	1.4080 to 1.4110 for PRIMER, 1.4905 to 1.4935 for ADHESIVE

9. 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 Agar Diffusion Test)
Based on the criteria of the protocol of ISO 10993-5

Sensitivity (Direct Buehler Sensitization Test)
Based on the criteria of the protocol of ISO 10993-10

Irritation (Direct Primary Oral (Buccal) Irritation Test)
Based on the criteria of the protocol of ISO 10993-10

The device is a dental restorative product and the device does come in contact with the body tissues (tooth - enamel, dentin) for more than 24 hours.

In conclusion, biocompatibility of BZF-29 is acceptable device from the biological evaluation result.

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

11. Comparison of Technology
The specifications that are important to determine substantial equivalency of a dental adhesive system are bond strengths associated to tooth structure (enamel and dentin) and other substrates. Furthermore, as shown in "Indication for use" it is also important to evaluate the equivalence of sealing property of dentin tubules.

Property		Requirements	Test results	
			G-Premio BOND Lot.1402081	BZF-29 Lot.1402081 (PRIMER) Lot.1907201G (ADHESIVE)
1	Bond strength to tooth structure	>10MPa for enamel	29.6 (±2.4)	40.6 (±6.3)
		>10MPa for dentin	34.2 (±2.5)	47.1 (±8.7)
2	Bond strength to metal	>10MPa for precious metal	21.3 (±4.3)	29.9 (±9.7)
		>10MPa for non-precious metal	28.8 (±1.5)	32.5 (±3.8)
3	Bond strength to ceramic and composite	>10MPa for porcelain	25.8 (±2.3)	23.3 (±4.3)
		>10MPa for composite	34.8 (±2.0)	30.7 (±2.2)
4	Sealing property of dentin tubules	Should be sealed dentin tubules when observed using SEM	Conformed	Conformed
Judgment			Conformed	Conformed

The bond strengths as noted above compare the predicate device (G-Premio BOND, K143140) to the subject device. In both enamel and dentin bonding, the results are equivalent. In addition, bond strength of subject device to other substrates was equivalent to the predicate bond strengths to enamel and dentin.

All the components of the applicant device, BZF-29, 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
Therefore, the subject device has been shown to be substantially equivalent to the predicate device.

The following differences may be noted between BZF-29 and the predicate devices:
- BZF-29 is a two component (PRIMER and ADHESIVE), light-cured bonding agent and G-Premio Bond is a one component, light-cured bonding agent. The additional component in BSF-29 is to enhance the bond strength.

12. Conclusion
Based on similarities in intended use, mode of action, chemical composition, and performance testing, BZF-29 is substantially equivalent to the selected predicate device, G-Premio BOND.

	Applicant device	Primary Device
Product category	Resin tooth bonding agent, Class II	Resin tooth bonding agent, Class II
Trade name	BZF-29	G-Premio BOND
510(k)	K200682	K143140
Product Code	KLE	KLE
Prescription/OTC	RX Only	RX Only
Manufacturer	GC Corporation	GC Corporation
Indication 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.	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.
Product description	BZF-29 is a two component (PRIMER and ADHESIVE), light-cured bonding agent available in each of 5 mL liquid bottle or 0.1ml unit dose.	G-Premio BOND is a one component, light-cured bonding agent available in a 5 mL liquid bottle or unit dose.
Chemical Composition	Functional monomers as methacrylates Acetone solvent Silica Water Accelerator	Functional monomers as methacrylates Acetone solvent Silica Water Accelerator
Biocompatibility	Biocompatibility testing was conducted according to ISO 10993-1 – Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process. - ISO 10993-5:2009 Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity. Statement of Conformity: 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. - ISO 10993-10:2010 Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization Statement of Conformity: Base on the criteria of the protocol, the test article meets the requirements of the ISO 10993-10 guidelines. (Sensitization) Based on the criteria of the protocol, the test article extracts are considered to be non-irritants to the buccal tissues of Golden Syrian Hamsters. (Irritation). Based on similarities in intended use, mode of action, chemical composition, and performance testing, and biocompatibility results, BZF-29 is substantially equivalent to the selected predicate device, G-Premio BOND.	All components in G-Premio BOND have been used in previous products such as G-ænial Bond, K082768, and Metal Primer II, K972594. We conclude that all of the data, such as the similarity of the components to the predicate device, the similarity of the principle operation and the similarity of the performance data, support the safety and effectiveness of the applicant new device as intended without biological evaluation tests, taking into account of the requirements of ISO 10993-1: 2009.
Technological Characteristics and Mode of action	The bonding mechanism is applying it to tooth structure, then bonding chemically and mechanically by polymerization of uncured methacrylate ester monomers.	The bonding mechanism is applying it to tooth structure, then bonding chemically and mechanically by polymerization of uncured methacrylate ester monomers.