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

November 20, 2018

Re: K180917
Trade/Device Name: GC Acrylic Primer
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: Class II
Product Code: KLE
Dated: August 23, 2018
Received: August 24, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mary S. Runner -S3

Digitally signed by Mary S. Runner -S3
Date: 2018.11.20 07:28:37 -05'00'

forTina Kiang, Ph.D.
Acting 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

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)*

K180917

Device Name

GC Acrylic Primer

Indications for Use *(Describe)*

Increases the adhesiveness of light-curing composites to conventional acrylic resins used in dental laboratory procedures (e.g., modification of denture teeth/denture base resins)

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."

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 5, 2018

2. Device Name:

Proprietary Name: GC ACRYLIC PRIMER
Classification Name: Resin tooth bonding agent
Device Classification: 21 CFR 872.3200 Class II
Product Code: KLE

3. Predicate Devices:

Product	Applicant	510(k) No.	Code No	Decision Date	Predicate
ECLIPSE BONDING AGENT	DENTSPLY International	K051707	KLE	06/15/2005	Primary
GRADIA with Composite Primer*	GC America Inc.	K001518	EBF	07/05/2000	Reference
G-BOND PLUS (G-aenial Bond)	GC America Inc.	K082768	KLE	10/21/2008	Reference
UNIFAST LC	GC America Inc.	K890829	EBG	04/17/1989	Reference

*GRADIA kit that includes Composite Primer

4. Description of Device:

GC ACRYLIC PRIMER is a primer which raises the adhesiveness to acrylic resin and composite resin. GC ACRYLIC PRIMER is intended to use for bonding acrylics to acrylic resin, composite to composite resin, and acrylics to composite resin respectively.

5. Packaging

GC Acrylic Primer Package:

- Bottle 6mL

6. Shelf Life

Shelf Life and Storage Conditions:

- Shelf Life 2 years
- Recommended for optimal performance, store in a cool and dark place. 4-25°C (39.2 - 77.0°F)

7. Indications for Use:

Increases the adhesiveness of light-curing composites to conventional acrylic resins used in dental laboratory procedures (e.g., modification of denture teeth/denture base resins)

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
- Application characteristics
- Refractive index
- Bond strength

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.

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.

Property	Requirements
Appearance	No contamination of foreign matter.
Application characteristics (coating properties)	Equivalent to reference standard.
Refractive index	1.398±0.003
Bond strength	10MPa≤

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

Table 5.1 Substantial equivalence to predicate devices

	Applicant device	Primary Device
Product category	Resin tooth bonding agent Denture relining, repairing, or rebasing resin	Resin tooth bonding agent Denture relining, repairing, or rebasing resin
Trade name	GC ACRYLIC PRIMER	ECLIPSE BONDING AGENT
Manufacturer	GC Corporation	DENTSPLY International
510(k) No.	-	K051707
Indications for Use	Increases the adhesiveness of light-curing composites to conventional acrylic resins used in dental laboratory procedures (e.g., modification of denture teeth/denture base resins)	ECLIPSE BONDING AGENT is indicated for use in enhancing the bond of acrylic teeth to acrylic removable denture bases.
Product description	GC ACRYLIC PRIMER is a primer which raises the adhesiveness to acrylic resin and composite resin. ACRYLIC PRIMER is intended to use for bonding acrylics to acrylic resin, composite to composite resin, and acrylics to composite resin respectively.	The device is intended for use in the dental laboratory, by trained technicians, for the purpose of facilitating a bond between plastic denture teeth and cured denture base resins.
Mode of action	The device consists of several kinds of monomers to be polymerized. Polymerization of methacrylate monomers is through chemical cure.	The ECLIPSE BONDING AGENT is a blend of reactive dimers and oligomers in a solvent vehicle. These reactive entities, once initiated, undergo polymerization across the interface between the teeth and the denture base resin to yield a strong and lasting bond. This formulation has been shown to be particularly effective in initiating and maintaining the bond between acrylic denture teeth and both pour and light-curable denture base resins.

Instruction for use	1. Preparation of adhesion area 2. Applying GC Acrylic Primer 3. Light curing 4. Layering and adhering of resin materials	1. Remove all wax from the teeth, making certain that no residual wax remains on the teeth. 2. Plug in the hot plate and set the temperature to 100 on the graduated faceplate. Allow the hot plate to preheat for at least ten (10) minutes. 3. Deglaze the ridge lap of each tooth as a minimal preparation. 4. Once the teeth have been ground-in, remove any residual resin from each tooth. 5. Shake the bottle of Eclipse Bonding Agent to ensure contents are thoroughly mixed. Pour enough bonding agent into the round metal container to completely saturate the foam and cover the bottom of the container to a depth of 1 mm. Maintain 1mm depth for all applications. 6. Use tweezers to place up to 14 prepared teeth into the holes so that the teeth are positioned with the ridge lap down and in contact with the liquid. Immediately replace the lid on the container. 7. Place the tooth-filled container inside the metal ring of the hot plate until the 40°C rectangle on the temperature strip turns green (normally in four (4) to six (6) minutes). 8. Using heat-resistant gloves, carefully remove the metal container from the hot plate after the prescribed warming interval and unplug the device. 9. Place the teeth on a clean paper towel for about 1minute until any residual liquid evaporates. 10. Set the teeth onto the baseplate using Eclipse Set-Up Resin. 11. Process the Eclipse Prosthetic Resin according to the Directions For Use
Technological Characteristics	The bonding mechanism is mechanically and chemically bond when monomers are photopolymerized.	The cornponents of ECLIPSE BONDING AGENT have been used in legally marketed devices or were found safe for dental use. We believe that the prior use of the initiator components in legally marketed devices, the data provided regarding the modifications to the marketed device, and the biocompatibility test results support the safety and effectiveness of ECLIPSE BONDING AGENT for the intended use.

10. Substantial equivalence:
    The curing mechanism of the applicant device and predicate device is substantially equivalent in principle. Therefore, the applicant device and 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 device.

11. Differences
    The following differences may be noted between GC ACRYLIC PRIMER and the predicate /reference devices.
    - GC ACRYLIC PRIMER is available for bonding light-cured composite resin and acrylic resin to composites, acrylics, while ECLIPSE BONDING AGENT is available for bonding acrylic resin to acrylic resin.
    - Slight difference in indications for use verbiage.
    - Regarding the mechanism of polymerization, GC ACRYLIC PRIMER uses a catalyst excited by light, whereas ECLIPSE BONDING AGENT does not use this catalyst.

12. Conclusion
    Based on similarities in intended use, mode of action, chemical composition, and performance testing, GC ACRYLIC PRIMER is substantially equivalent to the predicate device.