



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

October 9, 2015

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

Re: K151541
Trade/Device Name: G- Fix
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth shade resin material
Regulatory Class: II
Product Code: EBF
Dated: July 7, 2015
Received: July 8, 2015

Dear Mr. 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,

 Tina
Kiang -S

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 (if known): K151541

Device Name: G-FIX

Indications for Use:

1. Splinting mobile 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)



GC AMERICA INC.
3737 WEST 127TH STREET
ALSIP, ILLINOIS 60803
TEL (708) 597-0900
FAX (708) 371-5103

1. Submitter Information:

GC AMERICA INC.
3737 W. 127th Street
Alsip, IL 60803

Contact Person: Mark Heiss, D.D.S.
Phone: (708) 926-3090
Fax: (708) 926-9100
Date Prepared: June 8, 2015

2. Device Name:

Proprietary Name: G-Fix
Classification Name: Tooth shade resin material
Device Classification: Class II, 872.3690
Product Code: EBF

3. Predicate Devices:

Company	Device	510(k) No.	Date Cleared
GC America Inc.	GRADIA DIRECT Flo (UNIFIL FLOW)	K020342	03/28/2002

4. Description of Device:

G-Fix is a light-cured resin cement for splinting mobile teeth. G-Fix is used in combination with phosphoric acid as a pre-treatment agent of tooth surfaces.

5. Indications for Use:

1. Splinting mobile teeth

6. Technological characteristics:

All the components of the applicant device, G-Fix, have already been used in the predicate device. The curing mechanism of the predicate is polymerization of uncured methacrylate ester monomers. This reaction is caused by photo initiator system.

7. Performance Bench Tests

It is confirmed that the device conforms to the required specifications of ISO 4049:2009 and ISO/TS 11405: 2003 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
- Adhesion to tooth structure (Enamel)

8. Packaging

One (1) Dental Composite Dispensing Syringe 2.7g (2.0mL), 2 dispensing tips (plastic type), 1 light protective cover

Dispensing tip package:

30 dispensing tips (plastic type), 2 light protective covers

30 dispensing tips (needle type), 2 light protective covers

9. Shades

Clear and TC (Tooth Color)

10. Shelf Life Evaluation 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)

11. Biocompatibility

Biocompatibility studies were conducted based on ISO 10993-1, 10993-5, and 10993-10 for cytotoxicity, sensitivity, and irritation.

Results

Test	ISO standard	Results	Conclusion
Sensitivity	10993-10	As defined by the scoring system of Kligman, this is a Grade I reaction and the test article is classified as having weak allergenic potential.	Based on the criteria of the protocol, a Grade I sensitization rate is not considered significant and the test article meets the requirements of the ISO 10993-10 guidelines.
Cytotoxicity	10993-5	There was no biological reactivity of the cells exposed to the test article extract. The response obtained from the positive and negative control article extracts confirmed the suitability of the test system.	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.
Irritation	10993-10	The test article sites did not show a significantly greater biological reaction than the sites injected with the control article.	Based on the criteria of the protocol, the test article meets the requirements of the ISO 10993-10 guidelines.

In addition, according to ISO 10993-1, products currently on the market may be considered as it relates to product biocompatibility. There have been no major adverse events reported for G-Fix.

	Property	Standards	Requirements	Test results		Compare to Standard	Compare to Predicate Device
				G-Fix: Clear Lot No. 1103011G	GRADIA DIRECT Flo (UNIFIL FLOW): A1 Lot No. 1111211		
1	Sensitivity to ambient light	ISO 4049: 2009 5.2.7 Sensitivity to ambient light	Remain physically homogeneous.	Conformed	Conformed		
2	Depth of cure	ISO 4049: 2009 5.2.8 Depth of cure	Not less than 1.5 mm	5.6 mm	3.0 mm		
				5.6 mm	3.0 mm		
				5.7 mm	2.9 mm		
				5.7 mm	3.0 mm		
				5.7 mm	3.0 mm		
				5.7(0.1) mm	3.0(0.0) mm	Exceeds	Exceeds
3	Flexural strength	ISO 4049: 2009 5.2.9 Flexural strength	Greater than 80 MPa	100 MPa	96 MPa		
				89 MPa	101 MPa		
				99 MPa	99 MPa		
				93 MPa	93 MPa		
				90 Mpa	93 Mpa		
				94(5) MPa	96(3.2) MPa	Exceeds	Equal
4	Water sorption	ISO 4049: 2009 5.2.10 Water sorption and solubility	Less than 40 $\mu\text{g}/\text{mm}^3$	36.1 $\mu\text{g}/\text{mm}^3$	33.1 $\mu\text{g}/\text{mm}^3$		
				33.9 $\mu\text{g}/\text{mm}^3$	35.4 $\mu\text{g}/\text{mm}^3$		
				34.4 $\mu\text{g}/\text{mm}^3$	36.7 $\mu\text{g}/\text{mm}^3$		
				33.5 $\mu\text{g}/\text{mm}^3$	34.0 $\mu\text{g}/\text{mm}^3$		
				34.6 $\mu\text{g}/\text{mm}^3$	33.9 $\mu\text{g}/\text{mm}^3$		
				35(0.9) $\mu\text{g}/\text{mm}^3$	35(1.3) $\mu\text{g}/\text{mm}^3$	Exceeds	Equal
5	Solubility	ISO 4049: 2009 5.2.10 Water sorption and solubility	Less than 7.5 $\mu\text{g}/\text{mm}^3$	0.8 $\mu\text{g}/\text{mm}^3$	0.5 $\mu\text{g}/\text{mm}^3$		
				0.4 $\mu\text{g}/\text{mm}^3$	0.5 $\mu\text{g}/\text{mm}^3$		
				0.6 $\mu\text{g}/\text{mm}^3$	0.4 $\mu\text{g}/\text{mm}^3$		
				0.7 $\mu\text{g}/\text{mm}^3$	0.6 $\mu\text{g}/\text{mm}^3$		
				0.7 $\mu\text{g}/\text{mm}^3$	0.7 $\mu\text{g}/\text{mm}^3$		
				0.6(0.1) $\mu\text{g}/\text{mm}^3$	0.5(0.1) $\mu\text{g}/\text{mm}^3$	Exceeds	Equal
6	Color stability after irradiation and water sorption	ISO 4049: 2009 5.4 Color stability after irradiation and water sorption	No more than slight change in color	Conformed	Conformed	Equal	Equal
7	Adhesion to tooth structure (Enamel)	ISO/TS 11405: 2003 5.2.5 Shear bond strength	Greater than 5MPa	31 MPa	34 MPa		
				29 MPa	31 MPa		
				28 MPa	29 MPa		
				30 MPa	28 MPa		
				27 Mpa	32 MPa		
				29(1) MPa	31(2) MPa	Equal	Equal
					*This result was obtained by the combination with phosphoric acid and G-aenial Bond.		

	Applicant device	Comparative device	
Trade name	G-Fix	GRADIA DIRECT Flo (UNIFIL FLOW)	
Common Name	Light-cured resin cement for splinting mobile teeth	Light-cured Flowable composite restorative	Different*
Product Classification	Tooth Shade Resin Material	Tooth Shade Resin Material	Same
Company	GC Corporation	GC Corporation	Same
510(k) No.	-	K020342	
Indications for use	1. Splinting mobile teeth	1. Restoration of class I, II, III, IV, V cavities 2. Restoration of root surface caries 3. Restorations in deciduous teeth 4. Filling tunnel shaped cavities 5. Sealing hypersensitive areas 6. Liner / base / filling in cavity undercuts 7. Sealant 8. Fixing mobile teeth 9. Additions to composite restorations	Different Note: #8 of Comparative Device is same as applicant.
Product description	G-Fix is a visible-light-cured resin cement for fixing splinting mobile teeth . G-Fix is used in combination with phosphoric acid as a pre-treatment agent of tooth surfaces.	GRADIA DIRECT Flo (UNIFIL FLOW) is a light cured highly flowable composite filled in a dental syringe. The material is available in 7 shades.	Both light cured Polymer based material
Components	* Barium glass * Urethane dimethacrylate (UDMA) * Bisphenol A polyethoxy methacrylate (Bis-MEPP) * Phosphoric ester monomer * Silicon dioxide * Photo initiator * Pigment	* Fluoro-alumino-silicate glass * Urethane dimethacrylate (UDMA) * Dimethacrylate * Silicon dioxide * Photo initiator * Pigment	Components of new device are contained in predicate and device includes Phosphoric monomer that is common in this device type
Instructions for use	1. Preparations 2. Shade Selection 3. Preparation in case of tooth structure (apply phosphoric acid to the bonding surfaces of teeth for 30 seconds) 4. Preparation in case of restoration 5. Placement of G-Fix 6. Light Curing 7. Finishing and Polishing	1. Shade Selection 2. Cavity Preparation 3. Bonding treatment 4. Placement of GRADIA DIRECT Flo (UNIFIL Flo) 5. Light Curing 6. Finishing and Polishing	Different in that the indications are narrower than the predicate

Substantial equivalence:

The applicant device complies with the requirements of ISO 4049: 2009 (Dentistry - Polymer-based restorative materials) and ISO/TS 11405: 2003. The curing mechanism of the new and predicate devices is substantially equivalent in principle. Therefore, the new and predicate devices are the same in function, and similar in composition and intended use. This supports that the compatibility of the applicant device are substantially equivalent to the predicate devices. Components of the new device are commonly used in other restorative materials.

The applicant device shows one indication with predicate device which is "splinting mobile teeth."

Differences

Common Name – G-Fix description is different from predicate device even though product classification is the same.

The Indications for Use is different as clinically the product is used to splint teeth.

Comparison to performance and predicate device have been met or exceeded.

Product description is different as clinically this product is used to splint teeth (predicate is more general as a restorative).

Components - additional use of Bis-MEPP is to modify viscosity as use for splinting teeth. Phosphoric ester monomer added to allow for adhesion to enamel.

Instructions for Use is different as clinically the product is used to splint teeth (predicate is more general as a restorative).

Technological characteristics:

All the components of the applicant device, G-Fix, have already been used in the predicate device. The curing mechanism of the predicates is polymerization of uncured methacrylate ester monomers. This reaction is caused by photo initiator system.

Use of 10-MDP (phosphoric ester monomer) allows for adhesion to tooth structure without the need for additional use of dentin adhesive.

Conclusion

Based on formulation, testing and meeting and/or exceeding ISO standards related to performance, as well as meeting at least equivalence versus the predicate device, we find the applicant device to be substantially equivalent.