



July 9, 2020

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

Re: K193113
Trade/Device Name: GC Temp PRINT
Regulation Number: 21 CFR 872.3770
Regulation Name: Temporary Crown And Bridge Resin
Regulatory Class: Class II
Product Code: EBG
Dated: June 11, 2020
Received: June 12, 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

Indications for Use

510(k) Number (if known)

K193113

Device Name

GC Temp PRINT

Indications for Use (Describe)

1. Fabrication of temporary crowns, bridges, inlays, onlays and veneers
2. Fabrication of long-term temporary restorations

Type of Use (Select one or both, as applicable)

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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Section 5 – 510(k) Summary

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) 925-0373

Date Prepared: July 9, 2020

2. Device Name:

Proprietary Name: GC Temp PRINT
Classification Name: Temporary crown and bridge resin
Device Classification: Class II, 872.3770
Product Code: EBG
510(k) Number: K193113

3. Predicate Devices:

Product	Applicant	510(k) No.	Code No	Predicate	Decision Date
Resin for Temporary Crown & Bridge	Dentis Co., Ltd.	K180657	EBG	Primary Predicate	12/07/2018
TEMPSMART (MSN-006)	GC America Inc.	K141562	EBG	Reference Device	09/05/2014

4. Description of Device:

5. GC Temp PRINT is 3D printable light curing composite for temporary crown and bridge. The device consists of a paste delivered in a bottle. GC Temp PRINT is fabricated with certain Digital Light Processing/Stereolithography Apparatus (DLP/SLA) 3D printers and post cured with light curing device into dental restorations, which are then bonded to tooth structure with adhesive temporary cement.

GC Temp PRINT Package:
Bottle (500 g) -QTY: 1

Shades available:
Light, Medium and Bleach

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) away from high temperatures or direct sunlight.

6. Performance Bench Tests

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

- Depth of cure
- Flexural strength
- Water sorption
- Solubility

The applicant device complies with some requirements of ISO 10477 and Company specification (1AB-1500-3-10696(3)). (see table below).

Property	Standards	Requirements in ISO 10477: 2018 and/or Company specification (1AB-1500-3-10696(3))
1 Depth of cure	Company specification (1AB-1500-3-10696(3))	0.098 – 0.130 mm
2 Flexural strength	ISO 10477: 2018 5.4 Flexural strength (Fabricated by 3D Printer)	> 50 MPa
3 Water sorption	ISO 10477: 2018 5.6 Water sorption (Fabricated by 3D Printer)	< 40 µg/mm ³
4 Solubility	ISO 10477: 2018 5.7 solubility (Fabricated by 3D Printer)	< 7.5 µg/mm ³

7. 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.

8. Clinical Performance Testing

No clinical testing has been performed on this device.

9. Substantial equivalence

Both applicant and primary predicate device are categorized in same Code No. EBG and both curing mechanism are polymerization of uncured methacrylate oligomers. The products are a liquid photo-curable material that is polymerized by UV laser. Though primary predicate device reacts with UV light 405nm, the applicant device can be polymerized by UV light which is 405nm or shorter wavelength. After printing, both applicant and primary predicate device are treated by extra light curing in UV light box to make final polymerization.

Therefore, the new and predicate devices are the same in clinical function, and similar in composition and intended use. This supports that the compatibility and safety of the applicant device are substantially equivalent to the predicate device.

10. Differences

The following differences may be noted between the predicate device and GC Temp PRINT.

- Though primary predicate device indicates “Duration is less than 30 days in oral environment”, applicant device is for “long-term temporary restorations”.
- The chemical formula is not exactly the same between applicant device and predicate devices.

Table 5.1

	Applicant device	Primary Predicate Device	Reference Device
Product category	Light cured temporary crown and bridge resin, Class II 872.3770; EBG	Resin for temporary crown and bridge Class II 872.3770; EBG	Dual cured temporary crown and bridge resin Class II 872.3770; EBG
Trade name	GC Temp PRINT	Resin for Temporary Crown & Bridge (K180657)	TEMPSMART (MSN-006) K141562
Manufacturer	GC Manufacturing Europe N.V.	Dentis Co., Ltd.	GC Corporation
Indication for use	1. Fabrication of Temporary crowns, bridges, inlays, onlays and veneers. 2. Fabrication of long-term temporary restorations.	Resin for Temporary Crown & Bridge is indicated for the fabrication of temporary dental restorations in conjunction with extra-oral curing light equipment. Duration is less than 30 days in oral environment.	1. Fabrication of temporary crowns, bridges, inlays, onlays and veneers 2. Fabrication of long-term temporary restorations.
Product description	GC Temp PRINT is 3D printable light curing composite for temporary crown and bridge. The device consists of a paste delivered in a bottle. GC Temp PRINT is fabricated with certain Digital Light Processing/Stereolithography Apparatus (DLP/SLA) 3D printers and post cured with light curing device into dental restorations, which are then bonded to tooth structure with adhesive temporary cement.	The Resin for Temporary Crown & Bridge is made by Methacrylate Oligomer based on the Urethane Acrylate Oligomer with 0.01~0.1wt% inorganic filler. It has stored in a brown 1000ml of HDPE bottle. It contains materials with colors of A2 based on the shade guide. This Product is a liquid photo-curable material that is polymerized by UV laser at 405nm. It can be used to make a tooth model with a photo-curable polymer that is cured by ultraviolet light. The liquid UV curing resin is cured at a specific wavelength (405nm) by the photo-initiator contained in the resin. Curing in a 3D printer is related to the conditions of the printer equipment, and is typically 0.1 to 0.010mm in thickness, and is output at a resolution of 0.1 to 0.03 mm on the x, y axis. This device should use ZENITH 3D Printer equipment using UV light source of Dentis Co., Ltd., and it is possible to produce three dimensional printed matter by curing lamination step by step a thicknesses of 100, 50 and 16 μ m.	TEMPSMART is a dual-cured, temporary crown and bridge resin. The components consist of Paste A and B, which are filled in a cartridge. Both pastes are automixed with a mixing tip.
Components	*Urethane dimethacrylate (UDMA) *Dimethacrylate *Silicon dioxide *Initiator *Pigment	The Resin for Temporary Crown & Bridge is made by Methacrylate Oligomer based on the Urethane Acrylate Oligomer with 0.01~0.1wt% inorganic filler.	<Paste A> * Composite filler * Urethane dimethacrylate (UDMA) * Dimethacrylate * Silicon dioxide * Initiator * Pigment

			<p><Paste B></p> <ul style="list-style-type: none"> * Urethane dimethacrylate (UDMA) * Dimethacrylate * Silicon dioxide * Initiator
Instructions for use	<p>Manufacturing process dental prosthetics Please refer to respective instructions of the additive manufacturing systems. List of additive manufacturing systems which support GC Temp PRINT can be downloaded from GC website - www.gceurope.com</p> <p>1. Digital Data Designing Use the instructed software related to the additive manufacturing system to modify and distribute the printed object and support structures on the virtual building platform. Create slice data with 50 µm and send it to the additive manufacturing device. Note: • Select the proper print program for GC Temp PRINT including all relevant process parameters.</p> <p>2. Print processing Before pouring GC Temp PRINT into the reservoir of the additive manufacturing device, shake the GC Temp PRINT in the original bottle for approximately 2 minutes. After shaking, directly pour it into the reservoir and set both the reservoir and the platform in accordance with the additive manufacturing system instruction. Start printing. Note: Make sure your printing platform, reservoir, working space and device are cleaned properly according to the additive manufacturing system instructions. Dirty tools can cause defect and therefore failure of the printed restoration(s).</p>	<p>Indication for Use The Resin for Temporary Crown & Bridge and the predicate device have similar indications for use statements. Limitation on the duration of the subject device was intended to ensure the performance of subject device by narrowing down the allowed terms of its prosthetic use. Such difference is not critical to the intended use of the subject device. Therefore it doesn't affect the safety and effectiveness of the device when used as labeled.</p>	<p>Fabricating temporary restorations</p> <ol style="list-style-type: none"> 1. Taking an impression <ol style="list-style-type: none"> 1) Take an impression using alginate or silicone impression material. Alternatively, temporary can be made using a laboratory-prepared thermoforming matrix. 2) Block out preparation undercuts. 2. Teeth preparation <ol style="list-style-type: none"> 1) Block out preparation undercuts. 2) Clean teeth preparation with water spray and lightly dry. 3) Lightly lubricate separating medium such as Vaseline on prepared teeth or resin core. 3. Dispensing <ol style="list-style-type: none"> 1) Before dispensing the first time from a new syringe or after a long interval in between use, bleed the pastes from the syringe. 2) Remove the cap of the syringe by rotating 1/4 turn anti-clockwise. Attach a Mixing Tip by aligning the V shaped notch on the rim of the mixing tip with the V shaped notch between the syringe barrels. Push firmly to attach the mixing tip. Then rotate the colored collar of the mixing tip 1/4 turn clockwise. 3) Discard first cm extruded before use. 4) Extrude material directly into the impression. <p>NOTE: The used mixing tip can be left on the syringe to serve as a storage cap until next use. For each application, place a new mixing tip.</p> 4. Fabricating a temporary restoration Fabricate a temporary crown and bridge according to timing showed below. Time indicate after start of mixing paste. Option1 Fabricating in the mouth

	<ul style="list-style-type: none"> • Color difference may occur if shaking is insufficient. • Avoid cross contamination with other products. • Before each printing process, gently stir the remaining material in the reservoir. <p>Before each printing process, check there is no polymerized area or visual evidence of contamination. If such, replace material.</p> <ul style="list-style-type: none"> • Replace material in the reservoir according the additive manufacturing system instructions. <p>3. Cleaning of the printed objects Carefully remove the printed restoration(s) from the printing platform. Do not remove the support structures under the object. For Cleaning, place the restoration(s) in a glass with Isopropanol solution (>96%), then place the glass in an ultrasonic water bath for 2min. Dry parts with compressed air. Repeat the cleaning procedure in a clean Isopropanol solution (>96%), then place in an ultrasonic water bath for 2 min. Important that the second rinse is done in a clean Isopropanol solution.</p> <p>After cleaning, check if the surface is still shiny, wet or sticky, which would indicate there is still Isopropanol or residual monomers on the printed object. If such, please repeat the cleaning procedure until restoration(s) are completely clean.</p> <p>Note:</p> <ul style="list-style-type: none"> • Do not rinse the restoration in an Isopropanol solution for more than 5 min. • Do not wipe the restoration(s) surface. • After cleaning, check the restoration for: <ul style="list-style-type: none"> o Inhomogeneous color distribution linked to the printing process o Deformation 		<table border="1"> <tr> <td data-bbox="1409 185 1503 266">0'00"~ 1'00"</td> <td data-bbox="1520 185 1923 266">Place TEMPSMART into the impression and reposition into the mouth.</td> </tr> <tr> <td data-bbox="1409 266 1503 324">1'00"~ 2'00"</td> <td data-bbox="1520 266 1923 324">Setting in the mouth.</td> </tr> <tr> <td data-bbox="1409 324 1503 600">Up to 2'00"</td> <td data-bbox="1520 324 1923 600">Remove the impression from the teeth. If necessary, tack cure with a light curing unit (GC G-Light) for 2seconds each tooth unit on the teeth. Remove the temporary restoration from the mouth and final cure with a light curing unit for 5seconds each tooth unit.</td> </tr> <tr> <td data-bbox="1409 600 1503 711">After final cure</td> <td data-bbox="1520 600 1923 711">Completely remove the oxygen inhibition layer from the surface of the temporary restoration with alcohol.</td> </tr> </table> <p>Option2 Fabricating on the model</p> <table border="1"> <tr> <td data-bbox="1409 764 1503 846">0'00"~ 1'00"</td> <td data-bbox="1520 764 1923 846">Place TEMPSMART into the impression and reposition on the model.</td> </tr> <tr> <td data-bbox="1409 846 1503 904">1'00"~ 3'00"</td> <td data-bbox="1520 846 1923 904">Setting on the model.</td> </tr> <tr> <td data-bbox="1409 904 1503 1125">Up to 3'00"</td> <td data-bbox="1520 904 1923 1125">Remove the impression from the model. Remove the impression from the model and final cure with an extraoral light curing oven for 1minute. Remove the temporary restoration from the model.</td> </tr> <tr> <td data-bbox="1409 1125 1503 1206">After final cure</td> <td data-bbox="1520 1125 1923 1206">Completely remove the oxygen inhibition layer from surface of the temporary restoration with alcohol.</td> </tr> </table> <p>Caution! When using a light curing unit on teeth, do not irradiate the temporary restoration more than 2 seconds for each surface because of high polymerization temperature.</p> <p>Note:</p>	0'00"~ 1'00"	Place TEMPSMART into the impression and reposition into the mouth.	1'00"~ 2'00"	Setting in the mouth.	Up to 2'00"	Remove the impression from the teeth. If necessary, tack cure with a light curing unit (GC G-Light) for 2seconds each tooth unit on the teeth. Remove the temporary restoration from the mouth and final cure with a light curing unit for 5seconds each tooth unit.	After final cure	Completely remove the oxygen inhibition layer from the surface of the temporary restoration with alcohol.	0'00"~ 1'00"	Place TEMPSMART into the impression and reposition on the model.	1'00"~ 3'00"	Setting on the model.	Up to 3'00"	Remove the impression from the model. Remove the impression from the model and final cure with an extraoral light curing oven for 1minute. Remove the temporary restoration from the model.	After final cure	Completely remove the oxygen inhibition layer from surface of the temporary restoration with alcohol.	
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	<p>o Defects like cracks or holes</p> <p>4. Post curing Perform a final polymerization using Labolight DUO. For use of other devices, we refer to respective instructions manufacturing systems which support GC Temp PRINT. This list can be downloaded from GC website - www.gceurope.com</p> <p>For final polymerization with Labolight DUO, cure for 3min on opposite from support side. Remove supports with a nipper and a carbide bur. Apply light for another 3 min from the other side to obtain final homogeneous polymerization. When using other manufacturers' light curing devices, refer to the respective manufacturer's instructions for use.</p> <p>Note:</p> <ul style="list-style-type: none"> • Make sure the Isopropanol solution is completely removed prior to post curing. • Do not apply light curing longer than instructed. • Do not use chair side hand-held type curing light for post curing. • Do not store the printed restoration(s) in direct sunlight. <p>5. Adjustment - Finishing - Gloss</p> <ol style="list-style-type: none"> 1. Carefully remove the remaining supports with a carbide bur. Too much pressure could break the restoration(s). 2. Shape and finish in the usual way. 3. When necessary, minor fit adjustments can be undertaken using UNIFAST III. 4. If required, modify shape by using a resin material such as G-aenial Flo X, G-aenial Universal Flo, UNIFAST III or grind to obtain proper occlusion. 5. Apply a coating agent OPTIGLAZE color following the manufacturer's instructions for use. <p>Note:</p>		<ol style="list-style-type: none"> 1) The above processing times are applicable to products which have been stored and processed at a temperature of 23° C / 74° F and at 50% relative humidity. Higher temperatures shorten these times, while lower temperatures extend them. The size of the restoration also has an impact on the setting times: as the size of the workpiece increases, the setting accelerates. 2) When light irradiating to the temporary bridge, irradiate the light onto the occlusal surface. 3) When final curing the temporary bridge with a light curing unit, irradiate the light by one tooth from both ends to of prevent deformation. <p>5. Finishing</p> <ol style="list-style-type: none"> 1) Remove the excess material using a fine carbide bur. 2) Check occlusion and if necessary, correct shape by using a resin material (TEMPSMART, G-aenial Flo, G-aenial Universal Flo, UNIFAST Trad) or grind to obtain proper occlusion. 3) Polish the surface of the temporary restoration using silicon polisher and goat's hair wheel. Alternatively, apply a coating agent (OPTIGLAZE). <p>Caution!</p> <p>Do not breathe in polishing dust. Use personal protective devices such as facemask and safety glasses.</p> <p>Note:</p> <ol style="list-style-type: none"> 1) When using a resin material (TEMPSMART, G-aenial Flo, G-aenial Universal Flo, UNIFAST Trad) for custom-shaping and shape correction, there usually is no need for a bonding agent. But completely remove saliva contaminated part using a carbide bur. And if necessary, apply a ceramic primer (CERAMIC PRIMER II) to the surface of the temporary restoration. 2) When using TEMPSMART for custom-shaping and shape correction, light cure the mixing paste with a light curing unit for 10 seconds.
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	<ul style="list-style-type: none"> Do not use GC Temp PRINT as an add on material. <p>When using a resin material such as G-aenial Flo X, G-aenial Universal Flo or UNIFAST III for custom-shaping and shape correction, there is no requirement for prior application of a bonding agent.</p> <p>6. Cementing Cement the completed temporary restoration using FREEGENOL or equivalent temporary cement.</p>		<p>6. Cementing Cement using temporary cement.</p> <p>Note: Do not use eugenol cement because it will prevent polymerization of resin.</p> <p>Repairing / Modifying of temporary restorations</p> <ol style="list-style-type: none"> 1) Abrade the surface of the temporary restorations using carbide bur. 2) If necessary, apply a ceramic primer (CERAMIC PRIMER II) and dry with air. 3) Place a resin material (TEMPSMART, G-aenial Flo, G-aenial Universal Flo, UNIFAST Trad) and cure according to manufacturer's instructions. <p>Note: Completely remove saliva contaminated part using a carbide bur.</p>
Technological Characteristics and Mode of action	The curing mechanism is polymerization of uncured methacrylate ester monomers photo initiator. It is fabricated by using Additive manufacturing system (3D printer).	The subject device is a polymer that changes its properties when exposed to UV light. It conforms into a hardened polymeric material through a process called curing. Temporary dental restoration using resin is technologically useful applications for dental treatment.	The curing mechanism is polymerization of uncured methacrylate ester monomers by "mixing initiator(s) and activator(s)" and/or "photo initiator." It is fabricated manually.

10. Conclusion

Based on similarities in intended use, mode of action, chemical composition, and performance testing, GC Temp PRINT is substantially equivalent to the selected predicate devices.