Section 6 – 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

1. **Submitter Information:**
   GC AMERICA INC.
   3737 W. 127th Street
   Alsip, IL 60803
   Contact Person: Mark Heiss, D.D.S.
   Phone: (708) 897-4042
   Fax: (708) 897-4031
   Date Prepared: April 14, 2010

2. **Device Name:**
   Proprietary Name: GC Fuji Temp
   Classification Name: Dental Cement
   Device Classification: Class II, 872.3275
   Product Code: EMA

3. **Predicate Devices:**

<table>
<thead>
<tr>
<th>Company</th>
<th>Device</th>
<th>510(k) No.</th>
<th>Date Cleared</th>
</tr>
</thead>
<tbody>
<tr>
<td>GC America Inc.</td>
<td>Fuji I</td>
<td>K980695</td>
<td>4/13/98</td>
</tr>
<tr>
<td>GC America Inc.</td>
<td>Freegenol Temporary Pack</td>
<td>K842994</td>
<td>10/18/84</td>
</tr>
</tbody>
</table>

4. **Description of Device:**
   GC Fuji TEMP is a 2-paste type, glass ionomer provisional luting cement filled in separate syringes, and assembled in one cartridge. With use of Paste Pak Dispenser, GC Fuji TEMP can be dispensed with the appropriate paste ratio.

   The applicant device, GC Fuji TEMP is substantially equivalent to the predicate devices in its intended use. Fuji I is intended for final cementation. Freegenol Temporary Pack is intended for temporary cementation. Although the intended periods in oral are different, all devices are used as luting cements.

5. **Indications for Use:**
   - Temporary cementation of crowns and bridges
   - Provisional cementation of crowns and bridges on implant abutments

6. **Technological characteristics:**
   GC Fuji TEMP is a 2-paste type, glass ionomer provisional luting cement filled in separate syringes, and assembled in one cartridge. With use of Paste Pak Dispenser, GC Fuji TEMP can be dispensed with the appropriate paste ratio.
GC Fuji TEMP Paste A contains Fluoro-alumino-silicate glass (forming ionic bond with polyacrylic acid, and provides radiopacity and fluoride release), distilled water, viscosity modifying agents, anti-septic agent, and pigments. Paste B contains distilled water, Polycrylic acid (forming ionic bond with fluoro-alumino-silicate glass and calcium contained in tooth structure), radiopacity agent, pH adjusting agent, and viscosity modifying agents.

7. Summary of Physical tests:

<table>
<thead>
<tr>
<th>Property</th>
<th>Standards</th>
<th>Test methods</th>
<th>Requirements</th>
<th>Result-qualitative</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Appearance</td>
<td>ISO 9917-1: 2007 Dentistry - Zinc oxide/eugenol and zinc oxide/non-eugenol cements</td>
<td>Visually inspected before and after paste mixing</td>
<td>• Free from extraneous material • Homogeneous and smoothly consistent</td>
<td>Within spec set by standard</td>
</tr>
<tr>
<td>2 Film thickness</td>
<td>ISO 3107: 2004 Dentistry - Zinc oxide/eugenol and zinc oxide/non-eugenol cements, Section 6.4 Determination of film thickness</td>
<td>(150 (+/-) 2) N load is applied for 10 min, 90 sec after start of mix (N=5)</td>
<td>Less than 25µm</td>
<td>Within spec set by standard</td>
</tr>
<tr>
<td>3 Setting time</td>
<td>ISO 3107: 2004 Dentistry - Zinc oxide/eugenol and zinc oxide/non-eugenol cements, Section 6.2 Determination of setting time</td>
<td>Mixed cement is placed at 37 deg, 180 sec after end of mix. The time when needle fails to penetrate completely 2mm depth of cement is defined, counting from start of mix. (N=2)</td>
<td>4 to 10 min</td>
<td>Within spec set by standard</td>
</tr>
<tr>
<td>4 Compressive strength</td>
<td>ISO 3107: 2004 Dentistry - Zinc oxide/eugenol and zinc oxide/non-eugenol cements, Section 6.3 Determination of compressive strength</td>
<td>Specimens (6mm high, 4mm in diameter) compressed at 1mm/min (N=5)</td>
<td>Less than 35MPa</td>
<td>Within spec set by standard</td>
</tr>
<tr>
<td>5 Acid-soluble lead content</td>
<td>ISO 9917-1: 2007 Dentistry - Water-based cements - Part 1: Powder/liquid, Section 13.2 Acid-soluble lead content</td>
<td>Soaked in lactic acid solution (pH 2.74) for 24 hours. (N=5)</td>
<td>Less than 0.40mm</td>
<td>Within spec set by standard</td>
</tr>
</tbody>
</table>
6. Acid-soluble lead content
ISO 9917-1: 2007 Crushed cement after setting is soaked in diluted HCl solution for 16 hours. Eluted lead is detected by atomic absorption or equivalent method. (N=1)

7. Radiopacity
ISO 9917-1: 2007 Compared to aluminum (N=1)

*ISO 3107:2004 is referred in consideration of clinical use of GC Fuji TEMP, which is relatively used for temporary, although the formulation of GC Fuji TEMP doesn’t belong to zinc oxide/eugenol or zinc oxide/non-eugenol cements.

*ISO 9917-1: 2007 is referred in consideration of the formulation of GC Fuji TEMP, which is based on glass polyalkenoate. In that requirement, acid erosion for glass polyalkenoate cements is "Max. 0.17 mm". However, in view of provisional cementation, the criteria for zinc polycarboxylate cements are adopted.

<table>
<thead>
<tr>
<th>Property</th>
<th>Standards and test methods applied</th>
<th>Test method</th>
<th>Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Working time</td>
<td>Company Specification: AB-15-Q-301-493</td>
<td>The time when mixed cement becomes rubbery is defined as working time (from start of mix).</td>
<td>2min30sec - 3min30sec (given by the manufacturer)</td>
</tr>
<tr>
<td>3 Consistency</td>
<td>Company Specification AB-15-Q-301-493</td>
<td>0.5 mL of mixed cement is loaded with 120g for 10 minutes. Average of long axis and short axis are calculated.</td>
<td>27 - 37 mm (given by the manufacturer)</td>
</tr>
</tbody>
</table>

8. Description of Safety and Substantial Equivalence:
All the components of the applicant device, GC Fuji Temp, have already been used in the predicate devices which are legally marked for the same indications and the same type of tissue contact. This supports the compatibility of GC Fuji Temp and the safety of the applicant device is substantially equivalent to the predicate devices. The new device and predicate devices are similar in function, composition, and intended use.
Mr. Mark Heiss  
Director, New Business Development, Academic & Regulatory Affairs  
GC America, Incorporated  
3737 West 127th Street  
Alsip, Illinois 60803

Re: K101420  
Trade/Device Name: GC Fuji Temp  
Regulation Number: 21 CFR 872.3275  
Regulation Name: Dental Cement  
Regulatory Class: II  
Product Code: EMA  
Dated: August 24, 2010  
Received: August 25, 2010

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 go to http://www.fda.gov/AboutFDA/Centers~f'fices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health’s (CDRH’s) Office of Compliance. 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 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 Small Manufacturers, International and Consumer Assistance 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,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure
Indications for Use

510(k) Number (if known): __________

Device Name: GC Fuji TEMP

Indications for Use:

- Temporary cementation of crowns and bridges
- Provisional cementation of crowns and bridges on implant abutments

Prescription Use __X__ AND/OR Over-The-Counter Use __________
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[Signature]

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K101420