

120521



MAY 10 2012

GC AMERICA INC.  
3737 WEST 127TH STREET  
ALSIP, ILLINOIS 60803  
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Section 5 – 510(k) Summary

1. Submitter Information:

GC AMERICA INC.  
3737 W. 127<sup>th</sup> Street  
Alsip, IL 60803

Contact Person: Mark Heiss, D.D.S.  
Phone: (708) 926-3090  
Fax: (708) 597-6222

Date Prepared: February 17, 2012

2. Device Name:

Proprietary Name: GC BLUE SILICONE  
Classification Name: Dental Impression material  
Device Classification: 872.3660  
Product Code: ELW

3. Predicate Devices:

Product	Applicant	510(k) No.	Code No
Fit Checker Advanced	GC AMERICA, INC	K110871	ELW
Fit Checker II	GC AMERICA, INC	K032289	ELW
GC Fusion (EXA'lence)	GC AMERICA, INC	K041398	ELW

4. Description of Device:

GC BLUE SILICONE is available in a 2-part cartridge device in which part 1 is a base silicone paste and part 2 is a catalyst silicone.

5. Indications for Use:

GC BLUE SILICONE is a silicone impression material for fit check by detecting the high spots and pressure points of ceramic crowns, ceramic bridges, ceramic inlays and the occlusal surface.

6. Description of Safety and Substantial Equivalence:

The applicant device, GC BLUE SILICONE is equivalent to predicate device, Fit Checker II, in its intended use. The applicant device, GC BLUE SILICONE, is equivalent to the predicate device, Fit Checker Advanced and GC Fusion (EXA'lence) in its chemical compositions.



## 7. Test Methods

**Test standards and methods based on ISO standards**

	<b>Property</b>	<b>Standards</b>	<b>Test methods</b>	<b>Requirements</b>
1	Detail reproduction ( $\mu\text{m}$ )	ISO 4823: 2000(E) Classification: Light bodied consistency	Detail reproduction was measured by the detail reproduction test method in ISO 4823	20 $\mu\text{m}$
2	Elastic Recovery (%)	ISO 4823: 2000(E) Classification: Light bodied consistency	Elastic recovery was measured by the Elastic recovery test method in ISO4823	$\geq 96.5$
3	Strain in compression (%)	ISO 4823: 2000(E) Classification: Light bodied consistency	Strain in compression was measured by the Strain in compression test method in ISO 4823	2.0-20

## 8. Shelf Life Evaluation and Storage Conditions:

- Shelf Life 2 years
- Store in a cool and dark place. 15-25°C (60-77.0°F)

## 9. Packaging

Two cartridge package :

Cartridge 62g (48mL) x 1,

Mixing Tip II S x 2

Mixing Tip II SS x 2

Optional

1. CARTRIDGE DISPENSER II
2. MIXING TIP II SS Refill Package

Accessories necessary for proper functioning of the device:

Mixing tip II S



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Mark Heiss, DDS  
Director – New Business Development, Academic and Regulatory Affairs  
GC America, Incorporated  
3737 West 127<sup>th</sup> Street  
Alsip, Illinois 60803

MAY 10 2012

Re: K120521  
Trade/Device Name: GC Blue Silicone  
Regulation Number: 21 CFR 872.3660  
Regulation Name: Impression Material  
Regulatory Class: II  
Product Code: ELW  
Dated: February 17, 2012  
Received: February 21, 2012

Dear Dr. 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/CentersOffices/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" (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 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

Section 4 – Indications for Use Statement

Indications for Use

510(k) Number (if known): K120521

Device Name: GC BLUE SILICONE

Indications for Use:

GC BLUE SILICONE is a silicone impression material for fit check by detecting the high spots and pressure points of ceramic crowns, ceramic bridges, ceramic inlays and the occlusal surface.

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 OF  
NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K120521