



Food and Drug Administration  
10903 New Hampshire Avenue  
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Silver Spring, MD 20993-0002

Shandong Huge Dental Material Corporation  
Steven Song  
General Manager  
No. 68 Shanhai Road, Donggang District  
Rizhao City, 276800  
REPUBLIC OF CHINA

October 31, 2016

Re: K161851  
Trade/Device Name: Glass Ionomer Cement (Luting)  
Regulation Number: 21 CFR 872.3275  
Regulation Name: Dental Cement  
Regulatory Class: Class II  
Product Code: EMA  
Dated: July 6, 2016  
Received: July 6, 2016

Dear Steven Song:

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" (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 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,

A handwritten signature in black ink that reads "Susan Runno DDS, MA". The signature is written in a cursive style. A large, semi-transparent "FDA" watermark is visible behind the signature.

Tina 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

## Indications for Use

510(k) Number (if known)

Device Name

Glass Ionomer Cement (Luting)

Indications for Use (Describe)

Self-curing glass ionomer based radiopaque luting cement, for dental use only. Recommended indications:

- (1) Cementation of metal-based inlays, onlays, crowns and bridges;
- (2) Cementation of high strength (zirconia based) all ceramic crowns and bridges;
- (3) Cementation of posts and screws made of metal or high-strength ceramic;
- (4) Cementation of orthodontic bands;
- (5) Restoration of caries in unstressed area (Luting II only).

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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## 510 (k) Summary

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

**1. Date Summary Prepared:** Aug. 01, 2016

**2. Submitter Information:**

Name SHANDONG HUGE DENTAL MATERIAL CORPORATION  
 Address No. 68 Shanhai Road, Donggang District, Rizhao City,  
 Shandong Province, 276800, P.R. China  
 Telephone +86 633 2277285  
 Fax +86 633 2277298  
 Contact Mr. Steven Song  
 E-mail zhangyj@hugedent.com

**3. Device Name**

Trade name: Glass Ionomer Cement (Luting)  
 Common name: Glass Ionomer Cement  
 Classification name: Dental Cement

**4. Substantially Equivalent Device**

Table 2: Predicate Device Information			
Company Name	Device Name	510 (k) NO.	Substantially Equivalent (SESE) Decision Date
GC AMERICA, INC.	FUJI I	K980695	04/13/1998

No reference devices were used in this submission.

**5. Description of Device**

Glass Ionomer Cement (Luting) has two models: Luting I and Luting II. It is a device composed of various materials mainly including Silica, Alumina, Strontium Fluoride in the powder composition and Poly Carboxylic Acid in the liquid composition which intended to serve as luting to affix dental devices such as metal-based inlays, onlays, crowns, bridges, and orthodontic bands. It's a powder liquid system, with each part is packaged separately when not in

use. The basic operation principle of Glass Ionomer Cement (Luting) is acid-base reaction. The physical properties of Glass Ionomer Cement (Luting) see page 5-3.

## 6. Indications for use

Self-curing glass ionomer based radiopaque luting cement, for dental use only. Recommended indications:

- (1) Cementation of metal-based inlays, onlays, crowns and bridges;
- (2) Cementation of high strength (zirconia based) all ceramic crowns and bridges;
- (3) Cementation of posts and screws made of metal or high-strength ceramic;
- (4) Cementation of orthodontic bands;
- (5) Restoration of caries in unstressed area (Luting II only).

## 7. Summary of Physical and Chemical Properties Tests

List of standards used:

ISO 9917-1:2007 *Dentistry-- Water-based cements - Part 1: Powder/liquid acid-base cements*

Table 3: Summary of physical and chemical properties test		
Items per ISO 9917:2007	Pass/fail criteria	Conclusion
ISO 9917-1:2007 5.2 Components	5.2.1 Liquid Free from deposits or filaments on the inside of its container. No visible signs of gelation. 5.2.2 Powder Free from extraneous material. 5.3 Unset cement Homogeneous and of a smooth consistency.	Within spec set by standard
ISO 9917-1:2007 8.1 Net setting time	For luting: 1.5~8 min	Within spec set by standard
	For restoration: 1.5~6 min	
ISO 9917-1:2007 8.2 Film thickness	For luting: $\leq 25 \mu\text{m}$	Within spec set by standard
	For restoration: N/A	
ISO 9917-1:2007 8.3 Compressive strength	For luting: $\geq 50 \text{ MPa}$	Within spec set by standard
	For restoration: $\geq 100 \text{ MPa}$	
ISO 9917-1:2007 8.4 Acid erosion	For luting: $\leq 0.17 \text{ mm}$	Within spec set by standard
	For restoration: $\leq 0.17 \text{ mm}$	
ISO 9917-1:2007 8.6.2 Acid-soluble Lead content	For luting: $\leq 100 \text{ mg/kg}$	Within spec set by standard
	For restoration: $\leq 100 \text{ mg/kg}$	
ISO 9917-1:2007 8.7 Radio-opacity	The radio-opacity shall be at least equivalent to that for the same thickness of aluminium.	Within spec set by standard

## 8. Technological Characteristics:

The new device, Glass Ionomer Cement (Luting), has the same design, materials and chemical composition as the predicate device.

Comparison Items	New Device		Predicate Device		
	Glass Ionomer Cement (Luting)		FUJI I K980695		
1) Regulatory Classifications	same		same		
2) Indications for use	similar		similar		
3) Contraindications	same		same		
4) Composition of Materials	Mainly composed of powder: Silica, Alumina, Strontium Fluoride; Poly Carboxylic Acid Mainly composed of liquid: Poly Carboxylic Acid; Distilled Water		Mainly composed of powder: Silica, Alumina, Strontium Fluoride; Poly Carboxylic Acid Mainly composed of liquid: Poly Carboxylic Acid; Distilled Water		
5) Physical Properties	Items	Luting I	Luting II	Luting II (only as restoration materials)	FUJI I
	Powder /liquid (g/g):	1.6~1.8/1.0	1.5~1.7/1.0	2.1~2.2/1.0	1.8/1.0
	Mixing time (min., sec.):	45"	45"	45"	20"
	Working time (min., sec.):	≤3' 00"	2' 00"~3' 00"	1' 30"~2' 00"	2' 00"
	Net setting time (min., sec.):	1' 30"~8' 00"	1' 30"~8' 00"	1' 30"~6' 00"	4' 30"
	Film thickness ( μ m):	≤25	≤25	N/A	≤25
	Compressive strength (MPa):	≥50	≥50	≥100	≥50
6) Labeling	similar		similar		
7) Target Population	dental patients		dental patients		
8) Anatomical Site	on teeth		on teeth		
9) Where Used	used in hospital, dental clinic and relevant places		used in hospital, dental clinic and relevant places		
10) Human Factors	dental professional		dental professional		
11) Design	powder, liquid, powder scoop, mixing pads; acid-base reaction		powder, liquid, powder scoop, mixing pads; acid-base reaction		
12) Stability/Shelf Life	<b>Storage:</b> Store in a cool and dark place (4-25°C) (39.2-77.0°F). <b>Shelf life:</b> 2 years		<b>Storage:</b> Store in a cool and dark place (4-25°C) (39.2-77.0°F). <b>Shelf life :</b> 3 years		
13) Cautions	similar		similar		
14) Standards Met	similar		similar		
15) Biocompatibility	same		same		
16) Sterility	clean not sterile		clean not sterile		
17) Chemical Safety	similar		similar		

## **9. Summary of Biocompatibility**

The new device, Glass Ionomer Cement (Luting), is substantially equivalent to the predicate devices (K980695) that have been on the market for decades and with no clinical adverse events. The formulation of new device does not contain any new or non-conventional chemicals compared to the legally marketed predicate device.

We selected our Glass Ionomer Cement ( Filling II, shade: A3) as the representative model in biocompatibility tests and those biocompatibility test reports can be used in the biological evaluation of Glass Ionomer Cement (Luting). The main reason is that Glass Ionomer Cement (Luting) has the same chemical compositions of glass powder, raw material suppliers, function mechanism and manufacture process as Glass Ionomer Cement ( Filling II, shade: A3).

Biocompatibility tests were performed to satisfied the ISO 10993 standards. The test items include Cytotoxicity, Sensitization, Irritation, Systemic Toxicity, Subchronic Toxicity and Genotoxicity.

## **10. Summary of Substantial Equivalence**

As with the comparison shown in substantial equivalence discussion, these two devices are similar in almost all aspects. In addition, the new device adds indications for use compared to the predicate device, the minor differences in indications for use fall within the intended use of the predicate device and do not impact safety and effectiveness proved by the tests. The details of physical properties are slightly different, but these two devices are in equivalent to other legally marketed devices of this type. Regarding the shelf life, the performance of the new device is not adversely affected by aging in 3.5 years. In order to ensure the quality of products, we have choose 2 years as the shelf life for Glass Ionomer Cement (Luting).

It can be seen that the minor differences between the new device and the predicate device are not of significance and do not raise questions of safety and effectiveness as compared to the predicate device. SHANDONG HUGE DENTAL MATERIAL CORPORATION concludes that Glass Ionomer Cement (Luting) is substantially equivalent to the predicate device described herein.

## **11. Photo of the device**

The photo of the new device is presented in the following page.

