DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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 CN

March 3, 2017

Re: K160345
Trade/Device Name: Glass Ionomer Cement
Regulation Number: 21 CFR 872.3275
Regulation Name: Dental Cement
Regulatory Class: Class II
Product Code: EMA
Dated: February 24, 2017
Received: March 1, 2017

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,

For 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160345

Device Name
Glass Ionomer Cement (Filling)

Indications for Use *(Describe)*
Self-curing glass ionomer based radiopaque filling cement, for dental use only. Recommended Indications:
(1) Restoration of primary teeth.
(2) Restorations of Class III, V and limited Class I cavities.
(3) Base linings under composite and amalgam.
(4) Core build-up.

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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005_510 (k) Summary

Date Summary Prepared: Feb. 24, 2017

Submitter Information:

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Contact	Mr. Steven Song
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Device Name

Table 1: Device name	
Trade name	Glass Ionomer Cement (Filling)
Common name	Glass Ionomer Cement
Classification name	Dental Cement (21 C.F.R. 872.3275, Product Code: EMA)

Substantially Equivalent Device

Table 2: Predicate device information			
	Company Name	**Device Name**	**510 (k) No.**
Primary Predicate Device	GC AMERICA, INC.	FUJI II	K980682
Reference Predicate Device	SILMET, Limited	ProGlass Cements (ProGlass One, ProGlass Two, ProGlass Two LC, ProGlass Nine, ProGlass Plus, ProGlass Silver)	K101869
	Shandong Huge Dental Material Corporation	Glass Ionomer Cement (Luting)	K161851

Description of Device

Glass Ionomer Cement (Filling) has two types: Filling I and Filling II. It is a device composed of various materials including Silica, Alumina, Strontium Fluoride in the powder composition and Poly Carboxylic Acid in the liquid composition which intended to serve as a permanent or

temporary tooth filling or as base linings. It's a powder liquid system. The basic operation principle of Glass Ionomer Cement (Filling) is acid-base reaction. The physical properties of Glass Ionomer Cement (Filling) see page 5-4.

Intended for Use / including the indications for use

Self-curing glass ionomer based radiopaque filling cement, for dental use only.

(1) Restoration of primary teeth.

(2) Restorations of Class III, V and limited Class I cavities.

(3) Base linings under composite and amalgam.

(4) Core build-up.

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 4: Summary of physical and chemical properties test

Item	Standard	Requirements	Conclusion
Components	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. If the powder is coloured, the pigment shall be uniformly dispersed throughout the powder. 5.3 Unset cement Homogeneous and of a smooth consistency.	Within spec set by standard
Net setting time	ISO 9917-1:2007 8.1 Net setting time	For restoration: 1.5~6min	Within spec set by standard
Compressive strength	ISO 9917-1:2007 8.3 Compressive strength	For restoration: ≥100MPa	Within spec set by standard
Acid erosion	ISO 9917-1:2007 8.4 Acid erosion	≤0.17mm	Within spec set by standard
Acid-soluble Lead content	ISO 9917-1:2007 8.6.2 Acid-soluble Lead content	≤100mg/kg	Within spec set by standard
Radio-opacity	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

Technological Characteristics:

The new device has similar function, scientific concept, design, main materials and chemical composition as the predicate device.

Table 3: Device comparison table

Comparison Items	New Device	Primary Predicate Device	Reference Predicate Device	
	Glass Ionomer Cement (Filling)	K980682	K101869	K161851
1) Regulatory Classifications	21 C.F.R. 872.3275 Product Code: EMA Class II	21 C.F.R. 872.3275 Product Code: EMA Class II	21 C.F.R. 872.3275 Product Code: EMA Class II	21 C.F.R. 872.3275 Product Code: EMA Class II
2) Intended Use-including the indications for use	Self-curing glass ionomer based radiopaque filling cement, for dental use only. (1) Restoration of primary teeth. (2) Restorations of Class III, V and limited Class I cavities. (3) Base linings under composite and amalgam. (4) Core build-up.	FUJI II is a self-cure glass ionomer material intended for the use as a dental restorative for the following typical applications: 1. Restoration of primary teeth. 2. Core build-up. 3. Class III, V and limited Class I cavities.	Refer to page 5-6	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).
3) Contraindications /Side Effects	1. Pulp capping; 2. In rare cases the product may cause sensitivity in some people. If any such reactions are experienced, discontinue the use of the product and refer to a physician.	1. Pulp capping; 2. In rare cases the product may cause sensitivity in some people. If any such reactions are experienced, discontinue the use of the product and refer to a physician.	Pulp capping	1. Pulp capping; 2. In rare cases the product may cause sensitivity in some people. If any such reactions are experienced, discontinue the use of the product and refer to a physician.

Table 3: Device comparison table

Comparison Items	New Device	Primary Predicate Device	Reference Predicate Device	
	Glass Ionomer Cement (Filling)	K980682	K101869	K161851
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	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	(see table below)			
6) Standards Met	ISO 9917-1:2007; ISO 7405:2008; ISO 10993-1:2009/(R) 2013; ISO 10993-3:2014; ISO 10993-5:2009/(R) 2014; ISO 10993-10:2010; ISO 10993-11:2006/(R) 2010; ISO 14971:2007/(R) 2010; ISO 15223-1:2012; ISO 13485: 2003.	ISO 9917-1:1991(E)	ISO 9917-1: 2003	ISO 9917-1:2007; ISO 7405:2008; ISO 10993-1:2009/(R) 2013; ISO 10993-3:2014; ISO 10993-5:2009/(R) 2014; ISO 10993-10:2010; ISO 10993-11:2006/(R) 2010; ISO 14971:2007/(R) 2010; ISO 15223-1:2012; ISO 13485: 2003.

5) Physical Properties:

Items	Filling I	Filling II	K980682	K101869	K161851
Powder /liquid (g/g):	1.8~2.0/1.0	2.0~2.1/1.0	2.7/1.0	Refer to page 5-7	
Mixing time (min., sec.):	min. 1´00"	min.1´00"	min.1´00"		
Working time (min., sec.):	1´00"~2´00"	1´00"~2´00"	1´45"~2´00"		
Net setting time (min., sec.):	1´30"~6´00"	1´30"~6´00"	1´30"~6´00"		
Compressive strength (MPa):	min.100	min.100	min.100		

Summary of Biocompatibility

The new device, Glass Ionomer Cement (Filling), is substantially equivalent to the predicate devices 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 because it is the worst case scenario. In the meantime, the two types of our Glass Ionomer Cement (Filling) has the same chemical compositions, indications for use, function mechanism and manufacturing process.

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

Summary of Substantial Equivalence

As with the comparison shown in substantial equivalence discussion, these devices are same or similar in almost all aspects. The new device adds an indication for use compared to the primary predicate device (Base linings under composite and amalgam) which fall within the indication for use of the reference predicate device (K101869, “Base/liner”). The details of physical properties are slightly different, but these devices are in equivalent to other legally marketed devices of this type.

It can be seen that the minor differences between the new device and the predicate device are not of significance. Shandong Huge Dental Material Corporation concludes that Glass Ionomer Cement (Filling) is substantially equivalent to the predicate device.

Photo of the device

Indications for use of the reference predicate device (K101869)

Indications for use

Products	Indications for Use
ProGlass One	Cementation of all types of metal, porcelain fused to metal, resin crowns, inlays, onlays & bridges Cementation of orthodontic bands Cementation of stainless steel crowns or orthodontic appliances retained with stainless steel crowns Base/liner
ProGlass Two	Class III, V and limited class I cavities Restoration of primary teeth Core Build Up
ProGlass Two LC	Class III and V restorations Restoration of Cervical erosions and root surface caries Core Build Up Base/Liner
ProGlass Nine	Class I & II cavities Decidious teeth: final restorative for Class I, II and V Long term restorative in non-load bearing areas of Class I, II and V Intermediate restorative & sandwich material for heavy stress bearing Core build up material
ProGlass Plus	Metal-based restorations Ceramic inlays Reinforced ceramic crowns and bridges All kinds of acrylic/resin crowns, inlays, onlays and bridges
ProGlass Silver	Class I, limited Class II, temporary fillings Restoration of primary teeth Core Build Up Base/Liner

Physical characteristics of the reference predicate device (K101869)

	ProGlass One	ProGlass Two	ProGlass Two LC	ProGlass Nine	ProGlass Plus	ProGlass Silver
Powder /liquid	2.4 / 1.0	3.5 / 1.0	2.3 /1.0	4.1 / 1.0	1.5 / 1.0	4.0 / 1.0
Mixing time (sec)	30"	30"	30"	30"	30"	20"
Working time	2' 30" – 3"	1' 30" – 2'	3'	2' 30"	3'	1'40"
Setting Time (min.sec)	3'10"-	3' 10" – 3'	3'	3' 30"	3'	4'
Light Cure (sec)			20"			

Physical characteristics of the reference predicate device (K161851)

Items	Luting I	Luting II	Luting II (only as restoration materials)
Powder /liquid (g/g):	1.6~1.8/1.0	1.5~1.7/1.0	2.1~2.2/1.0
Mixing time (min., sec.):	45"	45"	45"
Working time (min., sec.):	≤3′ 00"	2′ 00"~3′ 00"	1′ 30"~2′ 00"
Net setting time (min., sec.):	1′ 30"~8′ 00"	1′ 30"~8′ 00"	1′ 30"~6′ 00"
Film thickness (μ m):	≤25	≤25	N/A
Compressive strength (MPa):	≥50	≥50	≥100