DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

April 5, 2016

Gaia Dental Products, Inc.
Weitao Jia
President
290 Pratt Street, Unit 2314
Meriden, Connecticut 06450

Re: K152652
Trade/Device Name: PackFil™ Resin Modified Glass Ionomer Restorative Cement
Regulation Number: 21 CFR 872.3275
Regulation Name: Dental Cement
Regulatory Class: II
Product Code: EMA, EBF
Dated: February 18, 2016
Received: February 24, 2016

Dear Weitao Jia:

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" (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 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 yours,

for Erin I. Keith, M.S.
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)*

K152652

Device Name

PackFil Resin Modified Glass Ionomer Restorative Cement

Indications for Use *(Describe)*

PackFil RMGI Restorative Cement is indicated for filling and restoration of tooth of following typical applications:

- Primary teeth restorations;
- Class I restorations;
- Class III and V restorations;
- Transitional restorations;
- Base liners or laminated/sandwich restorations;
- Selective core build-ups (>50% coronal tooth intact);

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary K152652

Submitter:

Gaia Dental Products, Inc.
290 Pratt Street, Unit 2314
Meriden, CT 06450 (203)
238-1181- Phone (203) 294-
0461 - Facsimile Weitao Jia -
Contact Person

Date Summary Prepared/modified: April 4, 2016

Device Name:

- Trade Name – PackFil™ Resin Modified Glass Ionomer Restorative Cement
- Common Name – Resin Modified Glass Ionomer Dental Cement
- Classification Name – EMA, Dental Cement, per 21 CFR § 872.3275
- Additional Product Code – EBF, Tooth Shade Resin Material

Devices for Which Substantial Equivalence is Claimed:

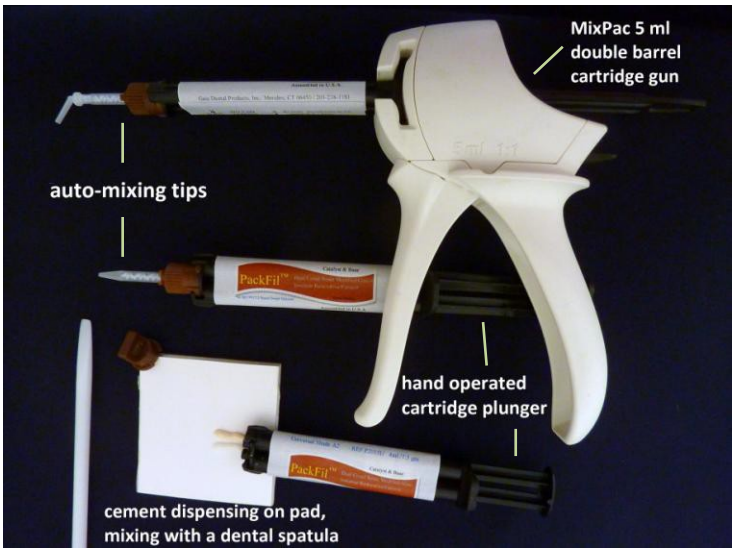
Primary Predicate: GC, Fuji Filling LC; K051427

Reference Predicate: 3M ESPE, Ketac Nano Glass Ionomer Restorative; K 052235

Device Description:

PackFil Resin Modified Glass Ionomer (RMGI) Restorative Cement is used by dental professionals and intended for filling and restoration of teeth. The subject device possesses triple curing mechanisms of conventional acid-base glass ionomer reaction, methacrylate resin chemical curing and light curable on demand. It is a tooth colored, radiopaque (equivalent of 2.5 mm of aluminum), two-part paste/paste resin modified glass ionomer restorative cement material, with each part is packaged separately when not in use. PackFil RMGI provides the common benefits typical of conventional glass ionomer materials, with the feature of being packable after the two parts mixed together. The filler content of this system is primarily a combination of traditional silane treated barium-boro-silicate glass filler and radiopaque acid reactive fluoroaluminosilicate glass filler having a hybrid particle size range from about 0.01 up to about 5 micrometers while the resin system has a combination of aqueous polyacrylic acid copolymer, phosphate and other polymerizable methacrylate resins.

PackFil RMGI Restorative Cement is packaged in a dual barrel cartridge system such as the dental MixPac®* 4 ml dual-barrel syringe or their equivalents. The picture below illustrates the mode of operation by using a matching auto-mixing tip attached to the syringe orifice and dispensed with help of using the MixPac® dispensing gun, or simply by hand; or the cement material can be pushed out with hand from the syringe on a mixing pad and subsequently mixed using a dental spatula and deliver, if desirable.



*MixPac® dual cartridge systems and dispensing accessories for dental use are products of Sulzer MIXPAC USA, Inc.

The PackFil Resin Modified Glass Ionomer Restorative Cement product is sold to clinicians in kits or refills. A Kit is essentially a set of the various shaded material bundled together. The clinician receives the devices packaged clean, but non-sterile, in appropriate, labeled containers with instructions for use enclosed.

Summary of Key Performance Testing Results – bench

	Self-cured	Light cured
Bonding Strength to Resin composite	18 MPa	22 MPa
Flexural Strength (MPa)	41 MPa	36 MPa
Compressive Strength (MPa)	245 MPa	230 MPa
Radiopacity	2.5 mm aluminum equivalent	
Self-cure working time	3 minutes	N/A

Self-cure setting time (From start of mixing)	6 minutes	N/A
Depth of cure (VLC for 20")	N/A	3 mm
Sensitivity to Ambient Light	N/A	>60 seconds

The performance data above satisfies the specification of ISO 9917-2: Dentistry – Water Based Cements – Part 2: Resin Modified Cements, where applicable.

Indications for Use:

PackFil RMGI Restorative Cement is indicated for filling and restoration of tooth of following typical applications:

- Primary teeth restorations;
- Class I restorations;
- Class III and V restorations;
- Transitional restorations;
- Base liners or laminated/sandwich restorations;
- Selective core build-ups (>50% coronal tooth intact);

Substantial Equivalence:

PackFil RMGI Restorative Cement is substantially equivalent to two other legally marketed devices in the United States. *PackFil RMGI* functions in a manner similar to and is intended for the same use as the Fuji Filling LC, marketed by GC America , and Ketac Nano Glass Ionomer Restorative, marketed by 3M ESPE. Every component used in the *PackFil RMGI* is commonly used in a variety of dental resin modified glass ionomers, resin composites, dental cements and dental bonding system products.

Similar to the predicate devices, *PackFil RMGI* is a catalyst/base paste-paste formulation, which combines a conventional acid-base glass ionomer cement reaction with modification of methacrylate resin chemistry which allows for self-cure and/or light cure. The application procedures and indications have not deviated from the prior generations of conventional restorative glass ionomer cements as well as the substantial equivalent predicate devices.

Table below listed in chart form, the similarities between the submitted device, PackFil Resin Modified Glass Ionomer Restorative Cement and the two predicate devices

Product	Description	Intended Use	Indications for Use	General Composition
PackFil Resin Modified Glass Ionomer Restorative Cement	A paste-paste form resin modified glass ionomer cement	Dental restorative as a filling and/or base liner	• Primary teeth restorations; • Class I restorations; • Class III and V restorations; • Transitional restorations; • Base liners or laminated/sandwich restorations; • Selective core build-ups (>50% coronal tooth intact);	Part A: A blend of aqueous polyacrylic acid, methacrylate and phosphate methacrylate resins, silane treated glass, silica, and polymerization component; Part B: A blend of methacrylate resins, ionomer glass, zinc oxide, calcium phosphate, silica, polymerization components and pigments
3M ESPE Ketac Nano Glass Ionomer Restorative K052235	A paste-paste form resin modified glass ionomer cement	Dental restorative as a filling and/or base liner	• Primary teeth restorations • Small Class I restorations • Class III and V restorations • Transitional restorations • Filling defects and undercuts • Laminate/Sandwich technique • Small core build-ups where at least 50% of coronal tooth structure is remaining for support	Part A: Silane-treated glass, zirconia and silica; ionomer glass; methacrylate resins. Photo- polymerization initiators. Part B: Silane-treated ceramic; methacrylate-modified co-polymer of acrylic and itaconic acids; methacrylate; water,
GC Fuji Filling LC K051427	A paste-paste form resin modified glass	Dental restorative as a filling and/or base liner	• Class V Restorations • Under posterior composites • Class III Restorations • Class I Pediatric Restorations and Core	Part A: Aluminoflurosilicate ionomer glass; methacrylate resins. Photo-initiator.

	ionomer cement		Build-Ups	Part B: Polyacrylic acid; water; methacrylate and filler.

Biocompatibility studies of *PackFil RMGI Restorative Cement* have been selected according to ISO 10993-1:2009. The following studies were performed with the results summarized below:

Test No.	ISO Test Method	Test Description	Result Summary
1	10993-5:2009	Cytotoxicity-L929MEM Elution	No cytotoxic effect
2	10993-10:2010, 3ed	Irritation – Intracutaneous Injection	Not more than the control article
3	10993-3:2003, 2ed	Genotoxicity – Mutation Study	Non-mutagenic
4	10993-10:2010, 3ed	Sensitization Maximization	No sensitization
5	10993-6:2007	Implantation - four weeks	Same as the negative control

Conclusion

Based upon the descriptive and comparative data provided within this submission, we have demonstrated substantial equivalency of PackFil Resin Modified Glass ionomer Restorative Cement material in design/composition, intended use, indications of use and performances including biocompatibility to its predicate devices. Therefore, this PackFil Resin Modified Glass Ionomer Restorative Cement is substantially equivalent to the declared predicate devices.