April 27, 2020

Reliance Orthodontic Products Inc.
Paula Wendland
Regulatory Affairs Manager
1540 West Thorndale Ave.
Itasca, Illinois 60143

Re: K193388
Trade/Device Name: GlassLok
Regulation Number: 21 CFR 872.3750
Regulation Name: Bracket Adhesive Resin and Tooth Conditioner
Regulatory Class: Class II
Product Code: DYH
Dated: February 25, 2020
Received: February 27, 2020

Dear Paula Wendland:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Srinivas “Nandu” Nandkumar, Ph.D.
Director
DHT1B: Division of Dental Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K193388

Device Name
GlassLok

Indications for Use *(Describe)*

GlassLok is intended for use as a dual cure glass ionomer band cement for use in an orthodontic or dental office.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Reliance Orthodontic Products, Inc.

Toll Free 1-800-323-4348 · Phone 630-773-4009 · Fax 630-250-7704
P.O. Box 678, 1540 West Thorndale Ave. · Itasca, IL · 60143 · U.S.A.

Section 5.0 510 (k) Summary

Note: This summary is provided in accordance with 21CFR807.92.

510(k) Submitter:	Reliance Orthodontic Products, Inc. Paul Gange, President/Owner
Address:	1540 West Thorndale Ave. Itasca, IL 60143 USA
Phone Number:	630-773-4009
Fax Number:	630-250-7704
Contact Person:	Paula Wendland, Regulatory Affairs Manager

Date 510(k) Summary was Prepared: 12/4/2019

Medical Device Name:

- Trade name – GlassLok
- Common name – Dual Cure Band Cement
- Classification name –Dental Cement (21CFR872.3275, Product Code EMA, Class II Device)

LEGALLY MARKETED DEVICES TO WHICH EQUIVALENCE IS CLAIMED (PREDICATE DEVICE) [807.92(a) (3)]:

- GC Fuji Ortho LC 510(k) K981461

This predicate has not been subject to a design related recall.

Reliance Orthodontic Products, Inc.

Toll Free 1-800-323-4348 · Phone 630-773-4009 · Fax 630-250-7704
P.O. Box 678, 1540 West Thorndale Ave. · Itasca, IL · 60143 · U.S.A.

5.1 DESCRIPTION OF THE APPLICANTS DEVICE:

GlassLok is intended for use as a dual cure glass ionomer band cement for use in an orthodontic or dental office. GlassLok can be used to bond molar bands to an enamel or metal substrate in a wet or dry field due to its hydrophilic properties. GlassLok is available in natural or blue shade (for easy disclosure at removal).

GlassLok is dispensed in a 2 part (powder and liquid) format with bottle dispensing. A 15cc and 25 cc liquid (in blue or natural shade) along with a 15gm or 100gm powder component will be available as separate components. A convenience kit will also be available in Blue or Natural shade in a starter or economy volume.

GlassLok powder is dispensed to a mixing pad using a measuring scoop and mixed with GlassLok liquid in a ratio of 2:1. The mixed GlassLok composite is then applied to the inside of an orthodontic band and applied to a properly prepared tooth structure. Working Time is 2 minutes and setting time is 5 minutes once the working time has expired. GlassLok can also be cured with a curing light for 20 seconds, if required for polymerization.

Associated accessories include a measuring scoop. Spatula and mixing pad.

5.2 INDICATIONS FOR USE AND POPULATION:

GlassLok is intended for use as a dual cure glass ionomer band cement for use in an orthodontic or dental office.

5.3 PREDICATE DEVICE:

GC Fuji Ortho™ LC 510(k) submission (K981461) dated 06/25/1998 is similar in intended use, handling and technology compared to the device described in this submission.

Reliance Orthodontic Products, Inc.

Toll Free 1-800-323-4348 · Phone 630-773-4009 · Fax 630-250-7704
P.O. Box 678, 1540 West Thorndale Ave. · Itasca, IL · 60143 · U.S.A.

5.4 COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE:

Property	GlassLok	Fuji Ortho™ LC
Intended Use/ Indications for Use	Dual Cure Glass Ionomer Band Cement	Light Cure Orthodontic Bonding Adhesive / Glass Ionomer dental cement.
Chemical Composition	Resin Modified Glass Ionomer Powder / Methacrylate based liquid	Resin Modified Glass Ionomer Powder / Methacrylate based liquid
Product Features	Bonds to metal and enamel surfaces. Band cement Bonds in a wet field Contains Fluoride Biocompatible	Bonding metal brackets and attachments. Band cementation only when extra band retention is desired Bonds in a wet field Fluoride releasing Biocompatible
Shelf Life	2 years at room temperature	2 years at room temperature
Dispensing Method	Bottle – Powder / Liquid	Bottle – Powder / Liquid
Method of Cure	Dual Cure (Light Cure and Chemical Cure)	Triple-Cure (Chemical Cure / Light Cure / Acid Based)

5.5 PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination:

GlassLok was tested against GC Fuji Ortho™ LC using a performance test method for shear bond strength. Testing resulted in similar or better

Reliance Orthodontic Products, Inc.

Free 1-800-323-4348 · Phone 630-773-4009 · Fax 630-250-7704
P.O. Box 678, 1540 West Thorndale Ave. · Itasca, IL · 60143 · U.S.A.

performance of GlassLok when compared to GC Fuji Ortho LC for shear bond strength to enamel and metal.
In addition, testing per ISO 9917-2:2017 was conducted on both GlassLok and GC Fuji Ortho LC resulting in similar results between the two products.

A biocompatibility evaluation was also conducted in accordance with ISO 10993 and ISO 7405:2018 for the composition of the GlassLok device and determined that the device did not directly or through the release of material constituents produce adverse local or systemic effects; it is not carcinogenic or mutagenic, and will not produce adverse reproductive or developmental effects. As a supplement to the biocompatibility evaluation, both cytotoxicity and oral toxicity testing was conducted on GlassLok.

5.6 CONCLUSION:
Based on nonclinical testing conducted for shear bond strength and testing conducted per ISO 9917-2:2017 resulting in similar performance, substantial equivalence was demonstrated between the GlassLok and the GC Fuji Ortho LC devices. In conjunction with biocompatibility demonstrated via ISO 7405:2018 and ISO 10993 evaluations, evidence has been submitted to demonstrate GlassLok is safe and equivalent to or better than the GC Fuji Ortho LC device in terms of performance as a band cement.