



Food and Drug Administration
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July 6, 2016

GC America, Inc.
Mark Heiss, D.D.S.
Director, Academic & Regulatory Affairs
3737 W. 127th St.
Alsip, Illinois 60803

Re: K153231

Trade/Device Name: G-Cem LinkForce, GC Dual Cure Activator, Try-in Paste, Multi
Primer

Regulation Number: 21 CFR 872.3275

Regulation Name: Dental Cement

Regulatory Class: II

Product Code: EMA, KLE, EBF

Dated: May 25, 2016

Received: May 27, 2016

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 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 yours,

 Tina
Kiang -S

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

Indications for Use Statement

510(k) Number : K153231

Device Name: G-Cem LinkForce

Indications for Use:

G-Cem LinkForce

1. Cementation of all types of all ceramic, resin and metal-based inlays, onlays, crowns and bridges.
2. Cementation of metal, ceramic, fiber posts, and cast post and cores.
3. Cementation of all ceramic and composite veneers (up to 2 teeth)
4. Permanent cementation of crowns and bridges on implant abutments.

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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use Statement

510(k) Number: K153231

Device Name: GC DUAL CURE ACTIVATOR

Indications for Use:

GC DUAL CURE ACTIVATOR

1. Cementation of indirect restorations.
2. Bonding of core build-ups made of light-curing composite or core build-up materials to tooth structure.
3. Bonding of resin cements and core build-up materials and self-cure composites to tooth structure.

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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use Statement

510(k) Number: K153231

Device Name: TRY-IN PASTE

Indications for Use:

TRY-IN PASTE

To evaluate the shade and the fitting of the restoration prior to permanent cementation.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use Statement

510(k) Number : K153231

Device Name: MULTI PRIMER

Indications for Use:

MULTI PRIMER

1. Priming of the adherend surfaces of indirect restorations made of glass ceramics, oxide ceramics, hybrid ceramics, composite and metal before luting procedures.
2. Intra-oral and extra-oral repair of fractured indirect restorations made of ceramics, hybrid ceramics and composites.

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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Section 5 - 510(k) Summary



GC AMERICA INC.
3737 WEST 127TH STREET
ALSIP, ILLINOIS 60803
TEL (708) 597-0900
FAX (708) 371-5103

1. Submitter Information:

GC AMERICA INC.
3737 W. 127th Street
Alsip, IL 60803

Contact Person: Mark Heiss, D.D.S.
Phone: (708) 926-3090
Alternate Contact: Lori Rietman
Phone: (708) 926-3092
Fax: (708) 926-9100

Date Prepared: May 25, 2016

2. Device Name:

Proprietary Name: G-Cem LinkForce, GC Dual Cure Activator, Try-In Paste and Multi Primer
Classification Name: Dental Cement
Device Classification: Class II, 872.3275
Product Code: EMA, KLE, EBF
510(k) Number: K153231

3. Predicate Devices:

Applicant Product	Product Type	Predicate Device	510(k) No.	Product Code	Predicate
G-CEM LinkForce	Cement	RelyX Ultimate	K110508	EMA	Primary
		LINKMAX	K001823	EMA	Reference
GC Dual Cure Activator	Dual Cure Activator	Scotchbond Universal	K110302	KLE	Primary
		LINKMAX Self Etching Primer A and Primer B	K001823	EMA	Reference
Try-In Paste	Try-In Paste	Variolink Veneer Try-In	K931309	EBF	Primary
		RelyX Try-In Paste	K002452	EMA	Reference
Multi Primer	Primer	Ceramic Primer II	K001823	EMA	Primary
		Metal Primer II	K972594	KLE	Reference

4. Description of Device:

G-CEM LinkForce

G-CEM LinkForce is a dual-cured resin cement. The components consists of Paste A and B, which are filled in a one-body syringe. Both pastes are automixed with a mixing tip. G-CEM LinkForce is available in 4 shades: Translucent, A2, Opaque, Bleach.

GC DUAL CURE ACTIVATOR

GC DUAL CURE ACTIVATOR is a primer to a tooth abutment. It must be used with G-Premio BOND (510(k) No. K143140).

TRY-IN PASTE

TRY-IN PASTE is a hue-conformity verification material. The product is placed into a dental restoration and set on an abutment tooth to verify hue and conformity. The product has a same color as G-CEM LinkForce.

MULTI PRIMER

MULTI PRIMER is a priming agent designed to treat the adherend surface of glass ceramic, oxide ceramic, hybrid ceramic, composite and metal restorations to promote a strong bond to resin-based materials as resin-based cements in case of luting procedures or direct composites in case of repairs.

5. Indications for Use:

G-CEM LinkForce

1. Cementation of all types of all ceramic, resin and metal-based inlays, onlays, crowns and bridges.
2. Cementation of metal, ceramic, fiber posts, and cast post and cores.
3. Cementation of all ceramic and composite veneers (up to 2 teeth)
4. Permanent cementation of crowns and bridges on implant abutments.

GC DUAL CURE ACTIVATOR

1. Cementation of indirect restorations.
2. Bonding of core build-ups made of light-curing composite or core build-up materials to tooth structure.
3. Bonding of resin cements and core build-up materials and self-cure composites to tooth structure.

TRY-IN PASTE

To evaluate the shade and the fitting of the restoration prior to permanent cementation.

MULTI PRIMER

1. Priming of the adherend surfaces of indirect restorations made of glass ceramics, oxide ceramics, hybrid ceramics, composite and metal before luting procedures.
2. Intra-oral and extra-oral repair of fractured indirect restorations made of ceramics, hybrid ceramics and composites.

6. Technological characteristics:

G-CEM LinkForce

G-CEM LinkForce is a dual-cured resin cement for indirect restorations, which is same as the primary and reference predicate devices. The curing mechanism of the predicate devices and applicant device is polymerization of uncured methacrylate ester monomers. This reaction is caused by photo initiator and chemical polymerization initiator systems.

GC DUAL CURE ACTIVATOR

All the components of the applicant device, GC DUAL CURE ACTIVATOR, have already been used in the reference predicate device. The bonding mechanism of the primary predicate device is applying it to tooth structure, then bonding chemically and mechanically by polymerization of uncured methacrylate ester monomers. This is the chemical component to initiate and complete chemical cure of G-Premio Bond. The chemical composition of the applicant device is such that it can also bond to tooth surfaces (like the predicate) as well as composites, hybrid ceramics, ceramics, and metals.

TRY-IN PASTE

TRY-IN PASTE is a hue-conformity verification material consisting of glycerol. The product is placed into a dental restoration and set on an abutment tooth to verify hue and conformity. The product has a same color as G-CEM LinkForce. TRY-IN PASTE is substantially equivalent to the predicate devices in that they are same in function and indications. Furthermore, the applicant device and primary predicate are both glycerol-based in composition.

MULTI PRIMER

Components in MULTI PRIMER have been used in primary predicate device CERAMIC PRIMER II and reference predicate METAL PRIMER II. The bonding mechanism of the applicant device is applying it to indirect restorations, then bonding chemically and mechanically by polymerization of uncured methacrylate ester monomers. This allows an active surface for the cement to bond to the primer.

7. Shelf Life Evaluation and Storage Conditions:

G-CEM LinkForce

- Shelf life: 2 years from date of manufacture
- Recommended for optimal performance, store in refrigerator (2-8°C / 35.6-46.4°F).

MULTI PRIMER

- Shelf life: 2 years from date of manufacture
- Recommended for optimal performance, store at room temperature (4-25°C / 39.2-77.0°F).

GC DUAL CURE ACTIVATOR

- Shelf life: 2 years from date of manufacture
- Recommended for optimal performance, store at room temperature (4-25°C / 39.2-77.0°F).

TRY-IN PASTE

- Shelf life: 2 years from date of manufacture
- Recommended for optimal performance, store at room temperature (4-25°C / 39.2-77.0°F).

8. Performance Bench Tests

It is confirmed that the applicant device conforms to the required specifications and is suitable for its intended use.

List of Standards used:

1. ISO 4049: 2009 Dentistry – Polymer-based restorative materials
For testing of G-CEM LinkForce
2. ISO11405: 2015 Dental materials - Testing of adhesion to tooth structure
For testing of G-Premio BOND with GC DUAL CURE ACTIVATOR

Performance testing includes the following:

Table 5.1 Performance testing properties

Standard	ISO 4049: 2009	ISO 11405: 2015
Property	<ul style="list-style-type: none">- Appearance- Film thickness- Working time- Setting time- Depth of cure- Flexural strength- Water sorption- solubility- Radiopacity	<ul style="list-style-type: none">- Adhesion to Dentin- Adhesion to Enamel

Table 5.2 Test standards and methods based on ISO 4049: 2009

	Property	Standards	Requirements
1	Film thickness	ISO 4049: 2009 5.2.2 Film thickness of luting materials	No greater than 50 µm
2	Working time	ISO 4049: 2009 5.2.4 Working time, Class 1 and 3 luting materials	No detectable change in its homogeneity
3	Setting time	ISO 4049: 2009 5.2.6 Setting time, Class 3 materials	Not more than 10 min
4	Depth of cure	ISO 4049: 2009 5.2.8 Depth of cure	Opaque shade: not less than 0.5 mm Other shade: not less than 1.5 mm
5	Flexural strength	ISO 4049: 2009 5.2.9 Flexural strength	Greater than 50 MPa
6	Water sorption	ISO 4049: 2009 5.2.10 Water sorption and solubility	Less than 40 µg/mm
7	Solubility	ISO 4049: 2009 5.2.10 Water sorption and solubility	Less than 7.5 µg/mm
8	Radiopacity	ISO 4049: 2009 5.5 Radiopacity	Greater than the same thickness of aluminum

Table 5.3 Test standards and methods based on ISO 11405: 2015

	Property	Standards	Requirements
1	Tensile bond strength to bovine dentin	ISO 11405: 2015 5.1.4 Shear bond strength	Greater than 5MPa
2	Tensile bond strength to bovine enamel	ISO 11405: 2015 5.1.4 Shear bond strength	Greater than 9MPa

9. Internal Company Test Method:

TRY-IN PASTE and MULTI PRIMER were tested in accordance with company specification test methods.

Table 5.4 Test methods based on Company Specification

	Property	Test method	Requirements
1	Film thickness	Company Specification	No greater than 50 µm

Table 5.5 Test methods based on Company Specification

	Property	Test method	Requirements
1	Tensile bond strength to porcelain	Company Specification	Greater than 10MPa
2	Tensile bond strength to zirconia	Company Specification	Greater than 10MPa
3	Tensile bond strength to Au-Ag-Pd alloy	Company Specification	Greater than 10MPa

10. Biocompatibility

G-CEM LinkForce

G-CEM LinkForce is a dual-cured resin cement. The components consists of Paste A and B, which are filled in a one-body syringe. Both pastes are automixed with a mixing tip. G-CEM LinkForce does come in contact with body tissues (tooth – enamel, dentin) for more than 24 hours. Biological testing results in accordance with ISO 10993-5 show the test article does not have a cytotoxic effect. Testing in accordance with ISO 10993-10, showed 0% sensitization rate, and was considered to be non-irritants to the buccal tissues. Biological testing as well as the similarity of components to the predicate device, the similarity of the principle operation, and the similarity of the performance data, support substantial equivalence.

GC DUAL CURE ACTIVATOR

GC DUAL CURE ACTIVATOR is a primer to a tooth abutment. It must be used to mix with G-Premio BOND (510(k) No. K143140). All components in GC DUAL CURE ACTIVATOR have been used in previous products such as LINKMAX SELF ETCHING PRIMER (K001823). GC DUAL CURE ACTIVATOR does come in contact with body tissues (tooth – enamel, dentin) for more than 24 hours. . Biological testing results in accordance with ISO 10993-5 show the test article does not have a cytotoxic effect. Testing in accordance with ISO 10993-10, showed 0% sensitization rate, and was considered to be non-irritants to the buccal tissues. Biological testing as well as the similarity of components to the predicate device, the similarity of the principle operation, and the similarity of the performance data, support substantial equivalence.

TRY-IN PASTE

TRY-IN PASTE is a hue-conformity verification material. TRY-IN PASTE does come in contact with body tissues (tooth – enamel, dentin). Furthermore, TRY-IN PASTE does not remain in the oral cavity as outlined in instructions for use. . Biological testing results in accordance with ISO 10993-5 show the test article does not have a cytotoxic effect. Testing in accordance with ISO 10993-10, showed 0% sensitization rate, and was considered to be non-irritants to the buccal tissues. Biological testing results as well as the similarity of components to the predicate device, the similarity of the principle operation, and the similarity of the performance data, support substantial equivalence.

MULTI PRIMER

MULTI PRIMER is a priming agent designed to treat the adherend surface of glass ceramic, hybrid ceramic (e.g. GC Cerasmart), zirconia, alumina, composite and metal restorations to promote a strong bond to resin-based materials as resin-based cements in case of luting procedures or direct composites in case of repairs. Components in MULTI PRIMER have been used in previous products such as CERAMIC PRIMER II (K001823) and METAL PRIMER II (K001823). . Biological testing results in accordance with ISO 10993-5 show the test article does not have a cytotoxic effect. Testing in accordance with ISO 10993-10, showed 0% sensitization rate, and was considered to be non-irritants to the buccal tissues. Biological testing as well as the similarity of components to the predicate device, the similarity of the principle operation, and the similarity of the performance data, support substantial equivalence.

11. Substantial equivalence:

G-CEM LinkForce

The applicant device, G-CEM LinkForce, complies with all the requirements of ISO 4049: 2009 (Dentistry - Polymer-based restorative materials).

The curing mechanism of the applicant and predicate devices is polymerization of uncured methacrylate ester monomers. The curing mechanism of the applicant and predicate devices is substantially equivalent in principle. The applicant and predicate devices are the same in function, and similar in composition and intended use. This supports that the compatibility of the applicant device is substantially equivalent to the predicate devices.

GC DUAL CURE ACTIVATOR

The applicant device, GC DUAL CURE ACTIVATOR, complies with all the requirements of ISO11405: 2003 (Dental materials - Testing of adhesion to tooth structure).

All the components of the applicant device, GC DUAL CURE ACTIVATOR, have already been used in the reference predicate device. The chemical composition of the applicant device is such that it can also bond to tooth surfaces (like the predicate) as well as composites, hybrid ceramics, ceramics, and metals. This supports that the compatibility of the applicant device is substantially equivalent to the predicate devices.

TRY-IN PASTE

TRY-IN PASTE is substantially equivalent to the predicate devices in that they are same in function, indications, and application. Furthermore, the applicant device and primary predicate are both glycerol-based in composition. This supports that the compatibility of the applicant device is substantially equivalent to the predicate devices.

MULTI PRIMER

Components in MULTI PRIMER have been used in primary predicate device CERAMIC PRIMER II and reference predicate METAL PRIMER II. The primary and reference predicate cover all indications of applicant device. This supports that the compatibility of the applicant device is substantially equivalent to the predicate devices.

12. Differences

The following differences may be noted between the applicant device and predicate devices:

G-CEM LinkForce

G-Cem Linkforce differs from RelyX Ultimate in terms of radiopacity. This occurs due to difference in glass fillers used in formulation.

GC DUAL CURE ACTIVATOR

GC Dual Cure Activator must always be used with G-Premio Bond (a 2-piece system) while the primary predicate is a single-component system. The applicant device can be used in dark cure mode.

TRY-IN PASTE

TRY-IN PASTE is not indicated to protect the etch pattern during try-in as indicated in the primary predicate. Slight variation of formulation (pigments) of applicant device results in varying shades.

MULTI PRIMER

MULTI PRIMER is a primer to glass ceramic, oxide ceramic, hybrid ceramic, composite and metal restorations but CERAMIC PRIMER II is without metal restoration, and Metal Primer II provides a bond between resin and metal.

	Applicant device	Comparative device (primary)	Comparative device (reference)
Indications for use	(G-CEM LinkForce) 1. Cementation of all types of all ceramic, resin and metal-based inlays, onlays, crowns and bridges. 2. Cementation of metal, ceramic, fiber posts, and cast post and cores. 3. Cementation of all ceramic and composite veneers (up to 2 teeth) 4. Permanent cementation of crowns and bridges on implant abutments.	(RelyX Ultimate) 1. Final cementing of all-ceramic, composite, or metal inlays, onlays, crowns and bridges; 2-3-unit Maryland bridges and 3-unit inlay/onlay bridges (excluded for patients with bruxism or periodontitis) 2. Final cementing of posts and screws 3. Final cementation of all-ceramic, or composite veneers 4. Final cementation of all-ceramic, composite, or metal restorations on implant abutments	(LINKMAX) 1. Bonding composite (micro-filled resin (MFR) or hybrid) inlays, onlays, bridges, veneers and crowns to tooth structure. 2. Bonding porcelain crowns, inlays, onlays and veneers to tooth structure. 3. Bonding precious or non-precious metal inlays, onlays, crowns and bridges to tooth structure.
Product description	G-CEM LinkForce is a dual-cured resin cement. The components consists of Paste A and B, which are filled in a one-body syringe. Both pastes are automixed with a mixing tip.	RelyX Ultimate is a dual-curing resin cement supplied in an automix syringe. It is used for the adhesive cementation of indirect restorations and available in various shades. RelyX Ultimate is used in combination with Scotchbond Universal Adhesive. The adhesive can be used either as a "Total Etch" or "Self-Etch" procedure. The additional etching of the tooth structure with Scotchbond Universal Etchant increases the adhesive strength of the adhesive even further. RelyX Ultimate contains bi-functional (meth) acrylate. The proportion of inorganic fillers is about 43% by volume; the grain size (D 90%) is about 13 µm. The mixing ratio, based on volume, is 1 part base paste :1 part catalyst.	LINKMAX is a dual cure composite resin designed to bond various types of prostheses to tooth structure. It uses a self-etching primer to bond to tooth structure and separate primers to bond to prostheses, core build-ups and posts made out of different materials. LINKMAX Paste Pak can be dispensed easily and accurately using the Paste Pak Dispenser.
Instructions for Use	1. Tooth preparation 2. Pre-treatment of the restoration 3. Dispensing cement paste 4. Cementation 5. Excess cement removal 6. Final set	1. Trial fitting of the restoration 2. Pre-treatment of restorations 3. Dosing and applying adhesive 4. Application of the cement 5. Removal of excess 6. Polymerization and shaping	1. Restoration preparation 2. Tooth preparation 3. Dispensing cement paste 4. Mixing cement paste 5. Cementation 6. Excess cement removal 7. Final set

Primary and reference predicate cover all indications of applicant device. The delivery system of the applicant device to predicate devices are same in function. Only difference in applicant device to predicate devices are slight change in glass fillers.

Table 5.7 Comparison of GC DUAL CURE ACTIVATOR to predicate device

	Applicant device	Comparative device (primary)	Comparative device (reference)
Indications for use	(GC DUAL CURE ACTIVATOR) 1. Cementation of indirect restorations. 2. Bonding of core build-ups made of light-curing composite or core build-up materials to tooth structure. 3. Bonding of resin cements and core build-up materials and self-cure composites to tooth structure.	(Scotchbond Universal) 1. All classes of fillings (according to Black) with light-curing composite or compomer filling materials 2. Cementation of indirect restorations when combined with RelyX Ultimate Adhesive Resin Cement 3. Cementation of veneers when combined with RelyX Veneer Cement 4. Bonding of core build-ups made of light-curing composite or core build-up materials 5. Bonding of dual-cure cements and core build-up materials and self-cure composites when combined with Scotchbond Universal DCA 6. Repair of composite or compomer fillings 7. Intraoral repair of composite restorations, porcelain fused to metal, and all-ceramic restorations without extra primer 8. Root surface desensitization 9. Sealing of cavities prior to cementation of amalgam restorations 10. Sealing of cavities and preparation of tooth stumps prior to temporary cementation of indirect restorations 11. Bonding of fissure sealants 12. Protective varnish for glass ionomer fillings	(LINKMAX Self-Etching Primer A & B) 1. Bonding composite (micro-filled resin (MFR) or hybrid) inlays, onlays, bridges, veneers and crowns to tooth structure. 2. Bonding porcelain crowns, inlays, onlays and veneers to tooth structure. 3. Bonding precious or non-precious metal inlays, onlays, crowns and bridges to tooth structure.
Product description	GC DUAL CURE ACTIVATOR is a primer to a tooth abutment. It must be used to mix with G-Premio BOND.	Scotchbond Universal is a single-component, light-curing adhesive which is available in L-Pop blisters for single dosing or in bottles for multiple doses.	Self-etching Primers are materials which are applied to dentin and enamel to enhance the adhesion of the tooth.
Instructions for Use	1. Tooth preparation 2. Pre-treatment of the restoration 3. Dispensing cement paste 4. Cementation 5. Excess cement removal 6. Final set	1. Trial fitting of the restoration 2. Pre-treatment of restorations 3. Dosing and applying adhesive 4. Application of the cement 5. Removal of excess 6. Polymerization and shaping	1. Restoration preparation 2. Tooth preparation 3. Dispensing cement paste 4. Mixing cement paste 5. Cementation 6. Excess cement removal 7. Final set

Primary and reference predicate cover all indications of applicant device. GC DUAL CURE ACTIVATOR is part of a 2-piece system and must be mixed with G-Premio Bond, while the primary predicate is a single-component.

Table 5.8 Comparison of TRY-IN PASTE to predicate device

	Applicant device	Comparative device (primary)	Comparative device (reference)
Indications for use	(TRY-IN PASTE) To evaluate the shade and the fitting of the restoration prior to permanent cementation.	(Variolink Veneer Try-In) Simulation of the shade of the permanent luting composite. Assessment of the accuracy of fit of the final restoration. Protection of the etch pattern during try-in, in case etching of the ceramic was performed in the laboratory.	(RelyX TRY-IN Paste) Color matching guide for RelyX Veneer cement.
Product description	TRY-IN PASTE is a hue-conformity verification material.	Variolink Veneer Try-In are based on the true influences of the cement on the esthetics of final restoration, rather than on the 'color' of the cement.	RelyX™ Try-In Paste are used to guide the dentist in the selection of the shade required for the final cementation.
Instructions for Use	<ol style="list-style-type: none"> 1. Prepare tooth 2. Dispense Try-in Paste onto internal surface of restoration. 3. Check fit and aesthetics of restoration. 4. Remove restoration. 5. Rinse out Try-in Paste 	<ol style="list-style-type: none"> 1. Prepare tooth 2. Dispense Try-in Paste onto internal surface of restoration. 3. Check fit and aesthetics of restoration. 4. Remove restoration. 5. Rinse out Try-in Paste 	<ol style="list-style-type: none"> 1. Prepare tooth 2. Dispense Try-in Paste onto internal surface of restoration. 3. Check fit and aesthetics of restoration. 4. Remove restoration. 5. Rinse out Try-in Paste

The primary predicate covers all the indications of the applicant device and is the same in function and application. The applicant and primary predicate are glycerol-based in composition.

Table 5.9 Comparison of MULTI PRIMER to predicate device

	Applicant device	Comparative device (primary)	Comparative device (reference)
Indications for use	(MULTI PRIMER) 1. Priming of the adherend surfaces of indirect restorations made of glass ceramics, oxide ceramics, hybrid ceramics, composite and metal before luting procedures. 2. Intra-oral and extra-oral repair of fractured indirect restorations made of ceramics, hybrid ceramics and composites.	(CERAMIC PRIMER II) 1. Treatment of ceramic prosthesis with phosphoric acid etchant.	(Metal Primer II) 1. resin cement to metal for metal inlays, crowns and bridges 2. opaque resin to metal for composite resin veneers and crowns 3. denture base to magnetic attachment 4. denture base resin to metal base, clasp or attachment 5. in-mouth repair of damaged crown and bridge veneers 6. repair of denture with metal base, clasp or attachment 7. bonding resin to metal orthodontic appliances
Product description	MULTI PRIMER is a priming agent designed to treat the adherend surface of glass ceramic, oxide ceramic, hybrid ceramic, composite and metal restorations to promote a strong bond to resin-based materials as resin-based cements in case of luting procedures or direct composites in case of repairs.	CERAMIC PRIMER II is a priming agent designed to firmly bond ceramic prostheses to tooth structure using resin adhesive cement.	METAL PRIMER II is a metal surface treatment material which provides a bond between the resin and metal in fabricating dental appliances such as bonding opaque material to metal framework for hard resin veneer crowns, bonding denture base resin to metal base, clasp, attachment, repair of denture and bonding orthodontic resin to metal orthodontic bracket and wire.
Instructions for Use	1. Preparation 2. Application	1. Preparation 2. Application	1. Preparation 2. Application

The applicant device can adhere to ceramic and metal whereas the primary predicate can adhere only to ceramic and the reference predicate can adhere only to metal. Primary and reference predicate cover all indications of applicant device.

13. Conclusion

G-CEM LinkForce

Based on similarities in intended use, mode of action, chemical composition, and performance testing, G-CEM LinkForce, is substantially equivalent to the primary predicate device RelyX Ultimate (K110508) and reference predicate device LinkMax (K001823).

GC DUAL CURE ACTIVATOR

Based on similarities in intended use, mode of action, chemical composition, and performance testing, GC DUAL CURE ACTIVATOR is substantially equivalent to the primary predicate device Scotchbond Universal (K110302), and reference predicate device LinkMax Self-Etching Primer A and Primer B (K001823).

TRY-IN PASTE

Based on similarities in intended use, mode of action, chemical composition, and performance testing, TRY-IN PASTE is substantially equivalent to the primary predicate device Variolink Veneer Try-In (K931309), and reference predicate device RelyX Try-In Paste (K002452).

MULTI PRIMER

Based on similarities in intended use, mode of action, chemical composition, and performance testing, MULTI PRIMER is substantially equivalent to the primary predicate device Ceramic Primer II (K001823) and reference predicate device Metal Primer II (K972594).