August 11, 2023

Prevest Denpro Limited
℅ Angela Blackwell
Senior Consultant
Blackwell Device Consulting
P.O. Box 718
Gresham, Oregon 97030-0172

Re: K231696
Trade/Device Name: Fusion Bond 5, Fusion Bond 7, Fusion Bond DC, Renew MDP, Renew Universal
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: Class II
Product Code: KLE
Dated: May 22, 2023
Received: June 12, 2023

Dear Angela Blackwell:

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,

Michael E. Adjodha -S

Michael E. Adjodha, M.ChE.
Assistant Director
DHT1B: Division of Dental and ENT 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231696

Device Name
Fusion Bond 5, Fusion Bond 7, Fusion Bond DC, Renew MDP, Renew Universal

Indications for Use *(Describe)*
Fusion Bond 5 is indicated for direct composite or compomer restorations, adhesive cementation, and composite repair.

Fusion Bond 7 is indicated for bonding of composites to tooth structure, core build up, and adhesive cementation of crown & bridges, including inlays and onlays.

Fusion Bond DC is indicated for direct light cure composite or compomer restorations, core build up, and adhesive cementation of crown & bridges, including inlays and onlays.

Renew MDP is indicated for bonding of dual cure, light cure or self cure composite or compomer restorations to tooth structure, treatment of hypersensitive teeth, and intraoral repairs of fractured restorations.

Renew Universal is indicated for direct bonding of light-cured composites, and compomers to tooth structure, bonding of dual-cured core build up composites to tooth structure as long as these materials are light-cured, intraoral repair of composite, metal-based and zirconia /alumina-based restorations, intraoral repair of ceramic restorations in combination with a silane coupling agent, treatment of hypersensitive teeth, and cavity sealing as a pretreatment for indirect restorations.

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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K231696

Fusion Bond 5, Fusion Bond 7, Fusion Bond DC, Renew MDP, Renew Universal
510(k) Summary
August 9, 2023

Name and Address: Prevest Denpro Limited
Unit II, Export Promotion Industrial Park
Bari Brahmana, Jammu 181133 India
Contact Person: Atul Modi
Email: prevestindia@gmail.com
Telephone: (941) 919 4280

Name of device: Fusion Bond 5, Fusion Bond 7, Fusion Bond DC, Renew MDP, Renew Universal
Trade Name: Fusion Bond 5, Fusion Bond 7, Fusion Bond DC, Renew MDP, Renew Universal
Common Name: dental bonding agent
Classification Name: Resin tooth bonding agents
CFR: 21 CFR 872.3200
Primary Product Code: KLE
Regulatory Class: II

Submission Contact:

Angela Blackwell
Blackwell Device Consulting
P.O. Box 718
Gresham, OR 97030-0172
(704)450-9934
angela@blackwelldevice.com

Device Description:

Prevest Denpro Tooth Bonding Agents attach different types of restorations to teeth.

Fusion Bond 5 is a light curing single component bonding agent. It primes and bonds in one step to attach restorations of composites, copomers, amalgams, and porcelains to tooth structures. Tooth structures should have a 37% phosphoric acid etchant applied before application of Fusion Bond 5.

Fusion Bond 7 is a light curing single component bonding agent. It etches, primes, and bonds in one step to attach restorations of composites, copomers, amalgams, and porcelains to tooth structures.

Fusion Bond DC is a dual cure bonding agent for bonding direct and indirect restorations. Enamel and dentin surfaces should be conditioned with 37% phosphoric acid etchant before application of Fusion Bond DC. It is a two component adhesive with bonding agent and activator.

Renew MDP is a light curing single component bonding agent. It combines etching, priming and bonding in one bottle. It is an ethanol-water based dental adhesive containing 10-Methacryloyloxydececyl Dihydrogen Phosphate (10-MDP) a functional monomer which helps in bonding to dentin and cut and un-cut enamel. Renew MDP works with light-cured, self-cured and dual-cured composite materials.

Renew Universal is a light curing single component bonding agent. It combines etching, priming and bonding. Renew Universal contains a combination of functional monomers such as 10-MDP and 4-META. Renew Universal works with light-cured and dual-cured composite materials.

Indications for Use:

Device Name	Indications
Fusion Bond 5	Fusion Bond 5 is indicated for direct composite or compomer restorations, adhesive cementation, and composite repair.
Fusion Bond 7	Fusion Bond 7 is indicated for bonding of composites to tooth structure, core build up, and adhesive cementation of crown & bridges, including inlays and onlays.
Fusion Bond DC	Fusion Bond DC is indicated for direct light cure composite or compomer restorations, core build up, and adhesive cementation of crown & bridges, including inlays and onlays.
Renew MDP	Renew MDP is indicated for bonding of dual cure, light cure or self cure composite or compomer restorations to tooth structure, treatment of hypersensitive teeth, and intraoral repairs of fractured restorations.
Renew Universal	Renew Universal is indicated for direct bonding of light-cured composites, and compomers to tooth structure, bonding of dual-cured core build up composites to tooth structure as long as these materials are light-cured, intraoral repair of composite, metal-based and zirconia /alumina-based restorations, intraoral repair of ceramic restorations in combination with a silane coupling agent, treatment of hypersensitive teeth, and cavity sealing as a pretreatment for indirect restorations.

Testing Summary:

Fusion Bond 5, Fusion Bond 7, Fusion Bond DC, Renew MDP and Renew Universal were tested for appearance, shear bond strength and curing time according to protocols based on ISO 29022:2013.

All test results met the criteria in standard.

Shelf life for Fusion Bond 5 and Fusion Bond 7 is 3 years. Shelf life for Fusion Bond DC, Renew MDP and Renew Universal is 2 years. All shelf life determinations use the same testing protocols as the characterization testing which are based on ISO 29022:2013. The predicate and reference devices use the same ISO standard for their testing. Their shelf lives are 3 years or are not given.

Primary Predicate Device: Prolink and Prolink SE K110403 from SIlmet

Additional Predicate Devices: Clearfil Photo Bond K943165 and Clearfil SE Bond 2 K131432 from Kuraray

Reference Devices Used for Ingredients:
Fusion Bond 5 - Adhese Universal (K133318) XP Bond Dual Cure Universal Total Etch Adhesive (K070538) Cal LC (K212457)
Fusion Bond 7 - Adper TM Prompt TM (K060684) Adhese Universal (K133318) Adhese Universal DC- (K210804) XP Bond Dual Cure Universal Total Etch Adhesive (K070538) Cal LC (K212457)
Fusion Bond DC - XP Bond Dual Cure Universal Total Etch Adhesive (K070538) Cal LC (K212457)
Renew MDP - Adhese Universal (K133318) Cal LC (K212457)
Renew Universal - Adhese Universal (K133318) Gluma Comfort Bond (K992985) Cal LC (K212457)

Substantial Equivalence:

The bonding agents have similar ingredients to the predicate and reference devices, the same indications for use, and similar physical parameter testing.

Resin Tooth Bonding Agents from Prevest Denpro

	Fusion Bond 5	Prolink K110403 from Silmet Predicate Device
Product Code	KLE	KLE
Indications for Use	Fusion Bond 5 is indicated for direct composite or compomer restorations, adhesive cementation, and composite repair.	Direct Composite or Compomer restorations Adhesive cementation Composite repair
Mechanism of Action	Bond restorations to teeth.	Bond restorations to teeth.
Applicable Standards	ISO 29022 - Dentistry – Adhesive – Notched-edge shear bond strength test	ISO 29022 - Dentistry – Adhesive – Notched-edge shear bond strength test
Composition	• Bisphenol A Glycidyl Methacrylate • Ethoxylated Bisphenol A Dimethacrylate • Urethane Dimethacrylate • Triethylene Glycol Dimethacrylate • 2-Hydroxethylmethyl acrylate • Camphorquinone • Ethyl-4 Di methyl amino benzoate • Tertiary butanol	• Bisphenol diglycidyl methacrylate • Ethoxylated Bisphenol A Dimethacrylate • Urethane Dimethacrylate • Triethylene Glycol Dimethacrylate • 2-Hydroxethylmethyl acrylate • camphoroquinone • Ethyl-4 Di methyl amino benzoate • Ethanol

	• Butylated hydroxy toluene (BHT) • 2-dimethyl amino ethyl Methyacrylate	• Acetone
Shear Bond Strength	Complies with ISO 29022 10 MPA	Complies with ISO 29022 14 MPa
Curing Time	Complies with ISO 29022 20-30 sec	Complies with ISO 29022 20 sec
Shelf Life	3 years	Not identified in 510k summary, package information says 3 years

	Fusion Bond 7	Prolink SE K110403 from Silmet Predicate Device
Product Code	KLE	KLE
Indications for Use	Fusion Bond 7 is indicated for bonding of composites to tooth structure, core build up, and adhesive cementation of crown & bridges, including inlays and onlays.	Bonding of composites to tooth structure Core Build up Adhesive cementation of crown & bridges, including inlays and onlays
Mechanism of Action	Bond restorations to teeth.	Bond restorations to teeth.
Composition	• Bisphenol A Glycidyl Methacrylate • Ethoxylated Bisphenol A Dimethacrylate • Urethane Dimethacrylate • Triethylene Glycol Dimethacrylate • Hydroxethylmethyl Phosphate • Camphorquinone • Ethyl-4 Di methyl amino benzoate • Tertiary butanol • Butylated hydroxy toluene (BHT) • 2-dimethyl amino ethyl Methyacrylate	• Bisphenol diglycidyl methacrylate • Ethoxylated Bisphenol A Dimethacrylate • Urethane Dimethacrylate • Triethylene Glycol Dimethacrylate • 2-Hydroxethylmethyl acrylate • camphoroquinone • Ethyl-4 Di methyl amino benzoate • Ethanol • Acetone
Applicable Standards	ISO 29022 - Dentistry – Adhesive – Notched-edge shear bond strength test	ISO 29022 - Dentistry – Adhesive – Notched-edge shear bond strength test

Shear Bond Strength	Complies with ISO 29022 25 MPA	Complies with ISO 29022 29MPa
Curing Time	Complies with ISO 29022 20-30 sec	Complies with ISO 29022 20 sec
Shelf Life	3 years	Not identified in 510k summary, package information says 3 years

	Fusion Bond DC	Clearfil Photo Bond K943165 from Kuraray Additional Predicate Device	Prolink K110403 from Silmet Predicate Device
Product Code	KLE	KLE	KLE
Indications for Use	Fusion Bond DC is indicated for direct light cure composite or compomer restorations, core build up, and adhesive cementation of crown & bridges, including inlays and onlays.	No 510k database file	Direct Composite or Compomer restorations Adhesive cementation Composite repair
Mechanism of Action	Bond restorations to teeth.	Bond restorations to teeth.	Bond restorations to teeth.
Composition	**Fusion Bond DC Bonding Agent** • Bisphenol A Glycidyl Methacrylate • Ethoxylated Bisphenol A Dimethacrylate • Urethane Dimethacrylate • Triethylene Glycol Dimethacrylate • Di Hydroxy Ethyl-P-Toluene • Camphorquinone • Ethyl-4 Di methyl amino benzoate • Tertiary butanol	**Universal Liquid:** • N-N diethyl-p Toludiene • Sodium benzene sulfinate • Ethyl Alcohol **Catalyst Liquid:** • Bisphenol A Glycidyl Methacrylate • 10-Methacryloyloxydecyl di hydrogen phosphate	• Bisphenol diglycidyl methacrylate • Ethoxylated Bisphenol A Dimethacrylate • Urethane Dimethacrylate • Triethylene Glycol Dimethacrylate • 2-Hydroxethylmethyl acrylate • camphoroquinone • Ethyl-4 Di methyl amino benzoate • Ethanol • Acetone

	• Butylated hydroxy toluene (BHT) **Fusion Bond DC Activator** • Bisphenol A Glycidyl Methacrylate • Ethoxylated Bisphenol A Dimethacrylate • Urethane Dimethacrylate • Triethylene Glycol • Benzyl Peroxide • Tertiary butanol • Butylated hydroxy toluene (BHT)	• 2-Hydroxethylmethyl acrylate • Hydrophobic Dimethacrylate • Benzyl Peroxide • DL-Camphorquinone	
Applicable Standards	ISO 29022 - Dentistry – Adhesive – Notched-edge shear bond strength test	ISO 29022 - Dentistry – Adhesive – Notched-edge shear bond strength test	ISO 29022 - Dentistry – Adhesive – Notched-edge shear bond strength test
Shear Bond Strength	Complies with ISO 29022 19 MPa	Complies with ISO 29022 15.9 MPa	Complies with ISO 29022 14 MPa
Curing Time	Complies with ISO 29022 20-30 secs	Complies with ISO 29022 10 sec	Complies with ISO 29022 20 sec
Shelf Life	2 years	Unknown	Not identified in 510k summary, package information says 3 years

	Renew MDP	Prolink K110403 from Silmet Additional Predicate Device	Clearfil SE Bond 2 K131432 from Kuraray Predicate Device
Product Code	KLE	KLE	KLE
Indications for Use	Renew MDP is indicated for bonding of dual cure, light cure or self cure composite or compomer restorations to tooth	Direct Composite or Compomer restorations Adhesive cementation Composite repair	[1] Direct restorations using light-cured composite resin [2] Cavity sealing as a pretreatment for indirect restorations

	structure, treatment of hypersensitive teeth, and intraoral repairs of fractured restorations.		[3] Treatment of exposed root surfaces [4] Treatment of hypersensitive teeth [5] Intraoral repairs of fractured restorations [6] Post cementation using a dual- or self-cured composite resin [7] Core build-ups using a light-, dual- or self-cured core material [8] Cementing inlays, onlays, crowns, bridges and veneers using a composite resin cement
Mechanism of Action	Bond restorations to teeth.	Bond restorations to teeth.	Bond restorations to teeth.
Composition	• Bisphenol A Glycidyl Methacrylate • Urethane Dimethacrylate • Triethylene Glycol Dimethacrylate • 2-Hydroxethylmethyl acrylate • Ethanol • DL Camphorquinone • Ethyl-4 Di methyl amino benzoate • Butylated hydroxy toluene (BHT) • 2-dimethyl amino ethyl Methyacrylate • DM water • 10-Methacryloxydecyl Dihydogen Phosphate	• Bisphenol diglycidyl methacrylate • Ethoxylated Bisphenol A Dimethacrylate • Urethane Dimethacrylate • Triethylene Glycol Dimethacrylate • 2-Hydroxethylmethyl acrylate • camphoroquinone • Ethyl-4 Di methyl amino benzoate • Ethanol • Acetone	• Bisphenol A Glycidyl Methacrylate • 10-Methacryloxydecyl Dihydogen Phosphate • 2-Hydroxethylmethyl acrylate • Hydrophobic aliphatic dimethacrylate • Dimethacrylate monomer • dl-Camphorquinone • Microfillers • Initiators • Accelerators
Applicable Standards	ISO 29022 - Dentistry – Adhesive – Notched-edge shear bond strength test	ISO 29022 - Dentistry – Adhesive – Notched-edge shear bond strength test	ISO 29022 - Dentistry – Adhesive – Notched-edge shear bond strength test

Shear Bond Strength	Complies with ISO 29022 21 MPa	Complies with ISO 29022 14 Mpa	Complies with ISO 29022 12.45 MPa or 25-30 MPa
Curing Time	Complies with ISO 29022 20-30 secs	Complies with ISO 29022 20 sec	Complies with ISO 29022 10 sec
Shelf Life	2 years	Not identified in 510k summary, package information says 3 years	Not identified in 510k summary, package information says 2 years

	Renew Universal	Prolink K110403 from Silmet Additional Predicate Device	Clearfil SE Bond 2 K131432 from Kuraray Predicate Device
Product Code	KLE	KLE	KLE
Indications for Use	Renew Universal is indicated for direct bonding of light-cured composites, and compomers to tooth structure, bonding of dual-cured core build up composites to tooth structure as long as these materials are light-cured, intraoral repair of composite, metal-based and zirconia /alumina-based restorations, intraoral repair of ceramic restorations in combination with a silane coupling agent, treatment of hypersensitive teeth, and cavity sealing as a pretreatment for indirect restorations.	Direct Composite or Compomer restorations Adhesive cementation Composite repair	[1] Direct restorations using light-cured composite resin [2] Cavity sealing as a pretreatment for indirect restorations [3] Treatment of exposed root surfaces [4] Treatment of hypersensitive teeth [5] Intraoral repairs of fractured restorations [6] Post cementation using a dual- or self-cured composite resin [7] Core build-ups using a light-, dual- or self-cured core material [8] Cementing inlays, onlays, crowns, bridges and veneers using a composite resin cement
Mechanism of Action	Bond restorations to teeth.	Bond restorations to teeth.	Bond restorations to teeth.
Composition	• Bisphenol A Glycidyl Methacrylate • Urethane Dimethacrylate • Triethylene Glycol Dimethacrylate	• Bisphenol diglycidyl methacrylate • Ethoxylated Bisphenol A Dimethacrylate • Urethane Dimethacrylate	• Bisphenol A Glycidyl Methacrylate • 10-Methacryloxydecyl Dihydogen Phosphate

	• 2-Hydroxethylmethyl acrylate • Ethanol • DL Camphorquinone • Ethyl-4 Di methyl amino benzoate • Butylated hydroxy toluene (BHT) • 2-dimethyl amino ethyl Methyacrylate • DM water • 4-2-Methacryloxyethyl Trimelltic	• Triethylene Glycol Dimethacrylate • 2-Hydroxethylmethyl acrylate • camphoroquinone • Ethyl-4 Di methyl amino benzoate • Ethanol Acetone	• 2-Hydroxethylmethyl acrylate • Hydrophobic aliphatic dimethacrylate • Dimethacrylate monomer • dl-Camphorquinone • Microfillers • Initiators • Accelerators
Applicable Standards	ISO 29022 - Dentistry – Adhesive – Notched-edge shear bond strength test	ISO 29022 - Dentistry – Adhesive – Notched-edge shear bond strength test	ISO 29022 - Dentistry – Adhesive – Notched-edge shear bond strength test
Shear Bond Strength	Complies with ISO 29022 21 MPa	Complies with ISO 29022 14 MPa	Complies with ISO 29022 12.45 MPa or 30 MPa
Curing Time	Complies with ISO 29022 20-30 secs	Complies with ISO 29022 20 sec	Complies with ISO 29022 10 sec
Shelf Life	2 years	Not identified in 510k summary, package information says 3 years	Not identified in 510k summary, package information says 2 years

Conclusion: Prevest Denpro tooth bonding agents are substantially equivalent to the predicate devices Prolink and Prolink SE K110403 from Silmet. They have the same indications, similar testing, and very similar ingredients. Both the subject devices and the predicate device have physical parameters which meet requirements of the relevant ISO standards. Shelf life testing is similar to the shelf life testing of predicate or reference device. Reference devices are included to cover any ingredients, or indications not covered by the predicate devices. Any differences in ingredients are minor and do not change the substantial equivalence.