March 3, 2026

Premier Dental Products Company
% Prithul Bom
Official Correspondent
Regulatory Technology Services, LLC
1000 Westgate Dr. Suite #510k
Saint Paul, Minnesota 55114

Re: K260682
Trade/Device Name: Bond-PR™ Universal Adhesive
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin tooth bonding agent
Regulatory Class: Class II
Product Code: KLE, LBH
Dated: March 2, 2026
Received: March 2, 2026

Dear Prithul Bom:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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, MChE, RAC, CQIA
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K260682

Please provide the device trade name(s).

Bond-PR™ Universal Adhesive

Please provide your Indications for Use below.

• Bonding of methacrylate-based light-, dual-, and self-cure composites, compomers, core build-up materials, sealants, and cements.
• Intraoral repair of composite and compomer restorations
• Root surface desensitization
• Cavity sealing prior to amalgam or temporary restorations
• Cementation of indirect restorations, including veneers, with resin cement
• Intraoral repair of composite, ceramic, porcelain-fused-to-metal, zirconia and other all-ceramic restorations.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) SUMMARY
Premier Dental's Bond-PR™ Universal Adhesive

1. Submitter Information

Premier Dental Products Company
1710 Romano Drive
Plymouth Meeting, PA 19462

Contact Person: Jessica Huang, Sr. Director of QA/RA
Phone: 610-239-6000
Facsimile: 610-239-6171

Date Prepared: January 16, 2026

2. Name of Device

Proprietary Name: Bond-PR™ Universal Adhesive
Common Name: Agent, Tooth Bonding, Resin
Review Panel: Division of Dental and ENT Devices (DHT1B)
Regulatory Class: 2
Product Code: KLE
Regulation Number: 21 CFR §872.3200
Classification Name: Resin tooth bonding agent

3. Predicate Devices

Product	Applicant	510(k) No.	Product Code	Predicate
ADH19-Scotchbond Universal Plus	3M Deutschland GmbH	K192961	KLE	Primary

4. Device Description

Premier's Bond-PR™ Universal Adhesive is a universal light-cure self-etch one component bonding agent with combines Etch, Primer and Adhesive into a single component for ease of application. Bond-PR™ Universal Adhesive is suitable for all direct and indirect bonding procedures and all etching techniques. It can also serve as a universal primer for all restoration materials. Bond-PR™ Universal Adhesive forms an excellent bond with dentin, enamel and any light-cure, self- or dual-cure composites, compomers, core build-up materials, sealants, and

cements. Premier Bond-PR™ Universal Adhesive is available in unit dose packages or in bottles for multiple usages.

Depending on the indication, the adhesive is used:
− In a self-etching procedure to enable quick treatment time and to reduce post-operative
sensitivities.
− With selective etch; etching solution is used to maximize the adhesion to the tooth enamel.
− In a total etch procedure with a prior phosphoric acid etching step of enamel and dentin.

Premier Bond-PR™ Universal Adhesive is free of bisphenol A(BPA) and BIS-GMA.

5. Indications for Use

Premier's Bond-PR™ Universal Adhesive has the following indications for use:

- Bonding of methacrylate-based light-, dual-, and self-cure composites, compomers, core build-up materials, sealants, and cements.
- Intraoral repair of composite and compomer restorations.
- Root surface desensitization.
- Cavity sealing prior to amalgam or temporary restorations.
- Cementation of indirect restorations, including veneers, with resin cement.
- Intraoral repair of composite, ceramic, porcelain-fused-metal, zirconia and other all-ceramic restorations.

6. Summary of Technological Characteristics

Premier Dental's Bond-PR™ Universal Adhesive is substantially equivalent to 3M's Scotchbond Universal Plus (ADH19, K192961) and has the same general technological characteristics, and principles of operation as the previously cleared predicate. Comparisons of the indications for use, composition, technological characteristics and principles of operation between the subject device Premier's Bond-PR™ Universal Adhesive and the predicate Scotchbond Universal Plus (ADH19, K192961) show that there are no new safety and efficacy risks. The subject device has no new/additional Indications for Use; the Indications for Use of subject device are within that of the predicate device. Both subject device and predicate device are formulated as light cured dental adhesives. Despite the minor differences in formulation/ ingredients, these products' performance and technological characteristics are equivalent. Thus,

the subject device, Premier's Bond-PR™ Universal Adhesive is substantially equivalent to the predicate Scotchbond Universal Plus (ADH19, K192961).

	Premier Bond-PR™ Universal Adhesive (Subject Device)	**ADH19- Scotchbond Universal Plus (K192961)**	**Equivalence Evaluation**
Target Users	Dental professionals	Dental professionals	Same
Indications for Use	• Bonding of methacrylate-based light-, dual-, and self-cure composites, compomers, core build-up materials, sealants, and cements. • Intraoral repair of composite and compomer restorations. • Root surface desensitization. • Cavity sealing prior to amalgam or temporary restorations. • Cementation of indirect restorations, including veneers, with resin cement. • Intraoral repair of composite, ceramic, porcelain-fused-metal, zirconia and other all-ceramic restorations.	Direct Indications: • Bonding for all methacrylate-based light-, dual-, and self-cure composite or compomer filling materials • Root surface desensitization • Bonding of methacrylate-based fissure sealants • Protective varnish for glass ionomer fillings • Repair of composite and compomer fillings • Sealing of cavities prior to placement of amalgam restorations Indirect Indications: • Cementation of indirect restorations in combination with RelyX™ Universal Resin Cement and other resin cements • Bonding for all methacrylate-based light-, self-, and dual-cure core build-up materials and cements • Cementation of veneers when combined with RelyX™ Veneer Cement	Similar. The Indications for Use of subject device are within that of the predicate device

		• Intraoral repair of composite restorations, porcelain fused to metal, and all-ceramic	
Classification Name	Resin tooth bonding agent	Resin tooth bonding agent	Same
Class	2	2	Same
Product Code	KLE	KLE	Same
Method of Polymerization	Light Cured	Light Cured	Same
Method of Application	Single component adhesive	Single component adhesive	Same
Composition	Dimethacrylate monomer, HEMA, phosphorylated methacrylate, ethyl alcohol, water, photo-initiator, co-initiator	Dimethacrylate monomer, HEMA, phosphorylated methacrylate, ethyl alcohol, silane treated silica, water, polymeric acid, photo-initiator, co-initiator	Similar
Technological Characteristics	Comply with ISO 29022 for Shear Bond Strength testing	Comply with ISO 29022 for Shear Bond Strength testing	Same
Sterility	Non-sterile	Non-sterile	Same
Shelf Life	At least 24 months	At least 24 months	Same
Delivery System	Bottle Unit Does	Bottle Unit Does	Same

7. Non-Clinical Testing

a. Performance

Performance tests for Premier's Bond-PR™ Universal Adhesive were conducted following on the FDA's recognized consensus standard for dental adhesives. Bench tests, including shear bond strength to etched and unetched detin and enamel (human and bovine), sandblasted zirconia, lithium disilicate and resin nano ceramic were performed on Premier's Bond-PR™ Universal Adhesive against the predicate device 3M Scotchbond Universal Plus (ADH19, K192961).

The subject device passed all evaluations, demonstrated physical characteristics equivalent to that of the predicated device (K192961). The testing results confirmed Premier's Bond-PR™ Universal Adhesive meets its intended physical and performance requirements.

b. Biocompatibility

To demonstrate the overall biological safety of Premier's Bond-PR™ Universal Adhesive, cytotoxicity, skin sensitivity, irritation, acute systemic toxicity, and genotoxicity tests were performed following ISO 10993 standards. Universal Adhesive showed no observed cytotoxicity, no skin sensitivity, no mucosa irritation, no systemic toxic reaction, and no genotoxicity.

8. Conclusions

Premier's Bond-PR™ Universal Adhesive is as safe and effective as the identified predicate device. Premier's Bond-PR™ Universal Adhesive has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. Premier Universal Adhesive does not raise new safety or effectiveness concerns, as these products are equivalent in performance and technological characteristics.

Thus, the subject device, Premier's Bond-PR™ Universal Adhesive is substantially equivalent to the predicate Scotchbond Universal Plus (ADH19, K192961).