June 3, 2026

American Orthodontics
% Dave Yungvirt
CEO
Third Party Review Group, LLC
7 Giralda Farms, Suite 120a
Madison, New Jersey 07940

Re: K261840
Trade/Device Name: BracePaste Prime Plus
Regulation Number: 21 CFR 872.3750
Regulation Name: Bracket adhesive resin and tooth conditioner
Regulatory Class: Class II
Product Code: DYH, KLE
Dated: June 1, 2026
Received: June 2, 2026

Dear Dave Yungvirt:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the Medical Device File (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 Management System Regulation (QMSR) (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.	K261840

Please provide the device trade name(s).

BracePaste Prime Plus

Please provide your Indications for Use below.

Indications for Use:
BracePaste Prime Plus is a light-cure primer / sealant intended to be used in the bonding procedure (direct or indirect) of orthodontic bondable devices by preparing the bonding surface during orthodontic treatment.

BracePaste Prime Plus is indicated for the following bonding surfaces: any dental structure containing zirconia, alumina, metals, glass ceramic, dentin, enamel, and composites.

Instructions for Use Statement:
Instructions for Use (IFU) for BracePaste Prime Plus are provided in paper form within the device packaging. An identical electronic IFU is available at www.americanortho.com.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☒ Children (2 years old to < 12 years old) ☒ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510(k) #: K261840

510(k) Summary

Prepared on: 2026-06-02

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	American Orthodontics
Applicant Address	3524 Washington Avenue Sheboygan WI 53081 United States
Applicant Contact Telephone	920.457.5051
Applicant Contact	Ms. Laura Richmond
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Correspondent Name	Third Party Review Group, LLC
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Correspondent Contact Telephone	973.232.0811
Correspondent Contact	Mr. Dave Yungvirt
Correspondent Contact Email	David.Yungvirt@fdathirdpartyreview.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	BracePaste Prime Plus
Common Name	Bracket adhesive resin and tooth conditioner
Classification Name	Adhesive, Bracket And Tooth Conditioner, Resin
Regulation Number	872.3750
Product Code(s)	DYH, KLE

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K161051	All-Bond Universal	KLE

Device Description Summary

21 CFR 807.92(a)(4)

American Orthodontics' BracePaste Prime Plus is a universal, resin based, light-curing primer that is intended for use in orthodontic treatment by a trained dental professional or orthodontist. It is used as a primer between the prepared bonding surface and bracket adhesive, where it facilitates the bonding.

The principles of operation for an orthodontic bonding agent are:
1. To serve as a "wetting" agent on bonding surface to allow for better adhesion;
2. To allow for orthodontic treatment by promoting the bond between orthodontic appliances and the bonding surface.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Indications for Use:
BracePaste Prime Plus is a light-cure primer / sealant intended to be used in the bonding procedure (direct or indirect) of orthodontic bondable devices by preparing the bonding surface during orthodontic treatment.

BracePaste Prime Plus is indicated for the following bonding surfaces: any dental structure containing zirconia, alumina, metals, glass ceramic, dentin, enamel, and composites.

Instructions for Use Statement:
Instructions for Use (IFU) for BracePaste Prime Plus are provided in paper form within the device packaging. An identical electronic IFU is available at www.americanortho.com.

Indications for Use Comparison 21 CFR 807.92(a)(5)

BracePaste Prime Plus and All-Bond Universal have similar indications for use. All-Bond Universal's indications for use statement is broader than the statement for BracePaste Prime Plus, in that it covers dental-specific use cases, such as dental restorations, in addition to use for orthodontic bonding. Based on use for orthodontic bonding, the indications for use of BracePaste Prime Plus is fully covered by the indications for use of All-Bond Universal. Additionally, both are indicated for orthodontic bonding on the following bonding surfaces: any dental structure containing zirconia, alumina, metals, glass ceramics, dentin, enamel, and composites. With respect to orthodontic bonding, there are no significant differences in the indications for use; any slight differences do not affect the safety and performance of BracePaste Prime Plus. Additionally, the slight differences in verbiage and indications were confirmed to be acceptable per Q-Sub (Q231676).

Technological Comparison 21 CFR 807.92(a)(6)

BracePaste Prime Plus and All-Bond Universal have the same technological characteristics through delivery system, chemical characteristics, physical characteristics, curing method, consistency, principle of operations, mechanism of action, and incorporation of similar materials.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Non-Clinical Performance Testing
The following non-clinical performance tests were conducted: Shear Bond Strength Test (ISO 29022:2013), Stability Study, Interaction with Accessories, Water Sorption and Solubility, Film Thickness, Solvent Evaporation.

Clinical Data: Not Applicable

The combination of in-house testing and side-by-side comparison performed by the original manufacturer has demonstrated the efficacy or suitability of BracePaste Prime Plus' intended purpose. Results of bench testing indicate that BracePaste Prime Plus performs as well as the predicate All-Bond Universal.

Both devices have the same intended use – to prepare the bonding surface and increase adhesion to the bonding surface of orthodontic treatment. Any slight differences do not affect the original function or intended purpose of the device.

Information contained in this 510(k) does not raise new questions or safety and effectiveness and demonstrates BracePaste Prime Plus is at least as safe and effective as the predicate.