August 27, 2024

American Orthodontics Corp.
% Dave Yungvirt
CEO
Third Party Review Group, LLC
25 Independence Blvd
Warren, New Jersey 07059

Re: K242537
Trade/Device Name: BracePaste Fluoride Sealant
Regulation Number: 21 CFR 872.3750
Regulation Name: Bracket adhesive resin and tooth conditioner
Regulatory Class: Class II
Product Code: DYH
Dated: August 24, 2024
Received: August 26, 2024

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 (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, 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242537

Device Name

BracePaste Fluoride Sealant

Indications for Use *(Describe)*

BracePaste Fluoride Sealant 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 to the etched enamel.

BracePaste Fluoride Sealant is indicated for the orthodontic treatment of malocclusions and craniofacial abnormalities as diagnosed by a trained dental professional or orthodontist.

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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K242537

510(k) Summary

21CFR807.92

Preparation Date: August 5th, 2024

Company Information:

American Orthodontics
3524 Washington Avenue
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Phone: 920-457-5051
Fax: 920-457-5773

Submitter Information:

Luke Hetue | Supplier Quality Engineer

Device Information:

Trade Name: BracePaste Fluoride Sealant
Common Name: Orthodontic Primer
Classification Name: Bracket Adhesive Resin and Tooth Conditioner
510(k) Number: unknown
Product Code: DYH
Regulation Number (21CFR): 872.3750

Predicate Device Information:

Product/Trade Name: Opal Seal
Classification Name: Bracket Adhesive Resin and Tooth Conditioner
510(k) Number: K090355
Product Code: DYH
Regulation Number (21CFR): 872.3750

Description of the Device:

American Orthodontics' BracePaste Fluoride Sealant is a light-curing primer that is intended for use in orthodontic treatment as diagnosed by a trained dental professional or orthodontist. The primer prepares the enamel during orthodontic treatment to increase adhesion to the bonding surface by wetting the bonding surface of the object to be bonded.

Indications for Use:

BracePaste Fluoride Sealant 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 to the etched enamel.

BracePaste Fluoride Sealant is indicated for the orthodontic treatment of malocclusions and craniofacial abnormalities as diagnosed by a trained dental professional or orthodontist.

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Substantial Equivalence Discussion:
BracePaste Fluoride Sealant has the following similarities to the legally marketed predicate Opal Seal (K090355):

- Same intended use, and
- Same technological characteristics through delivery system, chemical characteristics, curing method, and incorporation of similar materials.

The table below outlines the comparison of the predicate device (Opal Seal), and American Orthodontics' device (BracePaste Fluoride Sealant) to show Substantial Equivalence.

	Device Name / Manufacturer	
Element	**Device: Opal Seal** **Manufacturer: Ultradent Products, Inc.**	**Device: BracePaste Fluoride Sealant** **Manufacturer: American Orthodontics**
510(k) Number	K090355	unknown
Classification Code / Regulation Number	DYH 872.3750	DYH 872.3750
Indications for Use / Intended Use	Opal Seal is a light cure primer that is used when bonding orthodontic appliances to etched enamel.	BracePaste Fluoride Sealant 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 to the etched enamel. BracePaste Fluoride Sealant is indicated for the orthodontic treatment of malocclusions and craniofacial abnormalities as diagnosed by a trained dental professional or orthodontist.
Type and Duration of Tissue Contact	Long term use (used continuously for more than thirty days) Location - oral cavity, direct contact with tooth enamel Duration - greater than thirty days	Long term use (used continuously for more than thirty days) Location - oral cavity, direct contact with tooth enamel Duration - greater than thirty days
Delivery System	1.7g syringe	6mL Dropper Bottle
Material Type	Methacrylate based resin	Methacrylate based resin
Color	Light Yellow	Light Yellow
Physical Form	Liquid	Liquid
Storage Conditions	Under recommended storage conditions of 2 – 8 °C (36 – 46 °F), product has a shelf life of 18 months.	Under recommended storage conditions of 3 - 25 °C (38 - 77 °F), product has a shelf life of 3 years.
Curing Method	Light Activated	Light Activated
Presence of Fluoride	Yes	Yes
Sterile	Shipped Unsterile	Shipped Unsterile
Limits of Reuse	Tips are single use only	Do not re-use used/dispensed product

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Biocompatibility	Biocompatible per ISO 7405, ISO 10993-1 Refer to FDA 510(k) submission K090355.	Biocompatible per ISO 7405, ISO 10993-1 Refer to Section 15 – Biocompatibility

Performance Testing:

Clinical Performance Testing

No clinical performance testing has been conducted.

Non-Clinical Performance Testing

The following non-clinical performance tests were conducted:

1. Shear Bond Strength Test (ISO 29022:2013) – predicate device
2. Stability Study
3. Interaction with Accessories
4. Fluoride Measurements
5. Depth of Cure
6. Evaluation of Reapplication
7. Water Sorption and Water Solubility
8. Evaluation of Air Dry, Tack Cure

Non-Clinical Biocompatibility Testing

1. Cytotoxicity – Direct Contact
2. Cytotoxicity – Elution
3. Acute Systemic Toxicity Test
4. Genotoxicity – Bacterial Reverse Mutation Test
5. Genotoxicity – Mouse Lymphoma Assay
6. Irritation – Intracutaneous Reactivity
7. Sensitization – Delayed Hypersensitization Test
8. Subacute/Subchronic Systemic Toxicity Test

The combination of in-house testing and side-by-side comparison performed by the original manufacturer has demonstrated the efficacy or suitability to the intended purpose of the BracePaste Fluoride Sealant. Results of all conducted testing was found acceptable and does not raise any new issues of safety or effectiveness.

Conclusion:

The combination of in-house testing and side-by-side comparison performed by the original manufacturer has demonstrated the efficacy or suitability to the intended purpose of the BracePaste Fluoride Sealant. Results of bench testing indicate that BracePaste Fluoride Sealant performs as well as the predicate Opal Seal.

Both devices have the same intended use – to prepare the enamel and increase adhesion to the bonding surface during 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 Fluoride Sealant is at least as safe and effective as the predicate.