



American Orthodontics  
Andre Leak  
Regulatory Affairs Coordinator  
3524 Washington Avenue  
Sheboygan, Wisconsin 53081

October 15, 2018

Re: K181910

Trade/Device Name: BracePaste MTP Light Cure Primer  
Regulation Number: 21 CFR 872.3200  
Regulation Name: Resin Tooth Bonding Agent  
Regulatory Class: Class II  
Product Code: KLE, DYH  
Dated: July 17, 2018  
Received: July 17, 2018

Dear Andre Leak:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/DICE>) for more information or contact DICE by email ([DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

**Mary S. Runner -S3**

For Tina Kiang, Ph.D.

Acting 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

510(k) Number (if known)

K181910

Device Name

BracePaste MTP Light Cure Primer

Indications for Use (Describe)

Orthodontic Primers are intended to be used in the bonding procedure (direct or indirect) of brackets and tubes by preparing the enamel during orthodontic treatment to increase adhesion to wet or dry, normal and atypical enamel surfaces. The Primer wets the bonding surface of the object to be bonded (i.e. enamel, composite materials, etc.) to promote adhesion.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services  
Food and Drug Administration  
Office of Chief Information Officer  
Paperwork Reduction Act (PRA) Staff  
[PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov)

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

K181910

**510(k) Summary**

21CFR807.92

Page 5-1

**Preparation Date:** July 13, 2018**Company Information:**American Orthodontics  
3524 Washington Avenue  
Sheboygan, WI 53081  
Phone: 920-457-5051  
Fax: 920-457-5773**Submitter Information:**

Trang Adams / Regulatory Affairs Specialist

**Device Information:**Trade Name: BracePaste MTP Light Cure Primer  
Common Name: Orthodontic Primer  
Classification Name: Agent, Tooth Bonding, Resin  
510(k) Number: unknown  
Product Code: KLE  
Regulation Number (21CFR): 872.3200**Predicate Device Information:**Product/Trade Name: Transbond MIP Primer  
Classification Name: Agent, Tooth Bonding, Resin  
510(k) Number: K962785  
Product Code: KLE  
Regulation Number (21CFR): 872.3200**Description of the Device:**

American Orthodontics' BracePaste MTP Light Cure Primer is a light-curing primer that is intended to be used in direct or indirect bonding procedures of brackets and tubes. The primer prepares the enamel during orthodontic treatment to increase adhesion to wet or dry, normal and atypical enamel surfaces. The primer "wets" the bonding surface of the object to be bonded (i.e. enamel, composite materials, etc.) to promote adhesion. The primer will be available in liquid form in a dropper bottle.

The use of light-curing primers/adhesives has been around since 1970's. In the early 1980's, visible light-cured restorative materials were introduced. Hydrophilic primers were introduced in 1998. These primers were hydrophilic and bonded well to wet or dry enamel.

The primer contains Bisphenol a Diglycidyl Ether Dimethacrylate and 2-Hydroxyethyl Methacrylate resin compounds. These resin compounds are mixed with ethyl alcohol and water to form an aqueous solution. This solution has the hydrophilic characteristics necessary for the primer to adhere under wet conditions. Using a curing light, the irradiation causes the methylacrylate resins to undergo polymerization. This polymerization forms a bond between the etched enamel surface and the bracket adhesive

**Indications for Use:**

Orthodontic Primers are intended to be used in the bonding procedure (direct or indirect) of brackets and tubes by preparing the enamel during orthodontic treatment to increase adhesion to wet or dry, normal and atypical enamel surfaces. The Primer wets the bonding surface of the object to be bonded (i.e. enamel, composite materials, etc.) to promote adhesion.

**Substantial Equivalence Discussion:**

The Indications for Use statement for American Orthodontics' BracePaste MTP Light Cure Primer is not identical to the predicate in that the subject device's intended use is more descriptive. However, the differences do not alter the intended use of the device relative to the predicate. Both devices have the same intended use – to prepare the enamel for orthodontic treatment for bonding of brackets and tubes to increase adhesion.

Both devices have the same technological characteristics through delivery system, chemical characteristics, curing method, and incorporation of similar materials such as ethyl alcohol, Bisphenol a Diglycidyl Ether Dimethacrylate, 2-Hydroxyethyl Methacrylate, 2-Hydroxy-1,3-Dimethacryloxypropane, Diurethane Dimethacrylate, and Water.

The table below outlines the comparison of the predicate device (Transbond MIP Primer) and subject device (BracePaste MTP Light Cure Primer) to show substantial equivalence.

		<b>Device Name / Manufacturer</b>	
Element	Device: Transbond MIP Primer Manufacturer: 3M Dental Products Laboratory	Device: BracePaste MTP Light Cure Primer Manufacturer: American Orthodontics	
<b>510(k) Number</b>	K962785	unknown	
<b>Classification Code/ Regulation Number</b>	KLE 872.3200	KLE 872.3200	
<b>Intended Use</b>	This product is intended for use in orthodontic treatment.	Orthodontic Primers are intended to be used in the bonding procedure (direct or indirect) of brackets and tubes by preparing the enamel during orthodontic treatment to increase adhesion to wet or dry, normal and atypical enamel surfaces. The Primer wets the bonding surface of the object to be bonded (i.e. enamel, composite materials, etc.) to promote adhesion.	
<b>Delivery System</b>	6mL Dropper Bottle	6mL Dropper Bottle	
<b>Material Composition</b>	<ul style="list-style-type: none"> <li>• Ethyl Alcohol</li> <li>• Bisphenol a Diglycidyl Ether Dimethacrylate</li> <li>• 2-Hydroxyethyl Methacrylate</li> <li>• 2-Hydroxy-1,3-Dimethacryloxypropane</li> <li>• Diurethane Dimethacrylate</li> <li>• Water</li> </ul>	<ul style="list-style-type: none"> <li>• Ethyl Alcohol</li> <li>• Bisphenol a Diglycidyl Ether Dimethacrylate</li> <li>• 2-Hydroxyethyl Methacrylate</li> <li>• 2-Hydroxy-1,3-Dimethacryloxypropane</li> <li>• Diurethane Dimethacrylate</li> <li>• Water</li> </ul>	
<b>Chemical Characteristics</b>	Hydrophilic	Hydrophilic	
<b>Curing Method</b>	Light Activated	Light Activated	
<b>Consistency</b>	Liquid	Liquid	
<b>Bonding Type</b>	Direct/Indirect	Direct/Indirect	

**Performance Testing:**
Clinical Performance Testing

No clinical performance testing has been conducted.

Non-Clinical Performance Testing

The following non-clinical performance tests were conducted:

- *In vitro* Cytotoxicity Assay: Direct Cell Contact Test with MTP Light Curable Moisture Tolerant Primer (Study No. 176263)
- Interaction with Accessories: MTP Light Curable Moisture Tolerant Primer Compatibility
- Stability Test: MTP Light Curable Moisture Tolerant Primer Compatibility
- Test Report # 1701006; DIN 13990-2 Primer Testing
- Test Report # 1706013; DIN 13990-2: Bond Strength of MTP Primer with BracePaste
- Test Report # 1708011: Moisture Tolerant Primer Adhesive Strength Testing
- Performance Testing in accordance with ISO 29022:2013 Dentistry-Adhesion-Notched-edge shear bond strength test
- Test Protocol: Transbond MIP, 3M Unitek
- Test Protocol: MTP Light Curable Moisture Tolerant Primer

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 MTP Light Cure Primer. Results of bench testing indicate that BracePaste MTP Light Cure Primer performs as well as the predicate Transbond MIP Primer.

**Test Method Summary:**

Test Method	BracePaste MTP Light Cure Primer	Transbond MIP Primer
Average Bond Strength	38.94/mm <sup>2</sup>	38.70 N/mm <sup>2</sup>
Refractive Index (20.0°C)	1.4284	1.4441

**Conclusion:**

In summary, BracePaste MTP Light Cure Primer has the following similarities to the legally marketed predicate Transbond MIP Primer (K962785):

- Same intended use, and
- Same technological characteristics through delivery system, chemical characteristics, curing method, consistency, bonding type (direct/indirect) and incorporation of similar materials.