American Orthodontics
Ms. Trang Adams
Regulatory Affairs Specialist
American Orthodontics
3524 Washington Avenue
Sheboygan, Wisconsin 53081

October 14, 2016

Re: K160782
Trade/Device Name: Bracepaste Adhesive
Regulation Number: 21 CFR 872.3750
Regulation Name: Bracket Adhesive Resin and Tooth Conditioner
Regulatory Class: Class II
Product Code: DYH
Dated: September 9, 2016
Received: September 12, 2016

Dear Ms. Adams:

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. 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 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the
electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and Part 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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
510(k) Number (if known)
K160782

Device Name
BracePaste™ Adhesive

Indications for Use (Describe)
INDICATIONS FOR USE:
American Orthodontics’ BracePaste™ Adhesive is intended for use as an orthodontic bonding agent for Metal Brackets, Ceramic Brackets and Buccal Tubes to the tooth's surface.

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.

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Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
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."
**510(k) Summary**

**Preparation Date:** September 9, 2016

**Company Information:**
American Orthodontics  
3524 Washington Avenue  
Sheboygan, WI 53081  
Phone: 920-457-5051  
Fax: 920-457-5773

**Contact Information:**
Trang Adams / Regulatory Affairs Specialist

**Device Information:**
- **Trade Name:** BracePaste™ Adhesive  
- **Common Name:** Orthodontic Adhesive  
- **Classification Name:** Bracket Adhesive Resin and Tooth Conditioner  
- **Classification:** Class II  
- **Product Code:** DYH  
- **Regulation Number (21CFR):** 872.3750

**Predicate Device Information:**
- **Product/Trade Name:** Transbond™ XT  
- **Manufacturer:** 3M Unitek  
- **510(k) #:** K880393  
- **Classification:** Class II  
- **Classification Name:** Bracket Adhesive Resin and Tooth Conditioner  
- **Product Code:** DYH  
- **Regulation Number (21CFR):** 872.3750

**Description of the Device:**
BracePaste™ Adhesive is a light-curing adhesive used as an orthodontic bonding agent for metal brackets, ceramic brackets and buccal tubes. The adhesive will be offered in syringe and carpule containers which will allow a precise volume to be dispensed during orthodontic treatment.

The flow consistency (medium viscosity) of the adhesive allows for easy manipulation, yet does not allow bracket “drift” during placement. The flowable consistency also allows for precise dispensing and application of the adhesive.

The adhesive contains Bis GMA and Bis EMA as resin fillers. A combination of silanized strontium aluminum boron silicate glass and silanized silica is used as fillers (Silane Treated Quartz; Silane Treated Silica). The inorganic loading is approximately 72% by weight.

When exposed to light by a photoinitiator system, the methacrylate functionalities of the resin and fillers undergo a polymerization reaction which hardens or “cures” the adhesive. The adhesive in turn will create a “bond” to which the orthodontic appliance becomes attached to etched enamel surface.
Indications for Use:
American Orthodontics’ BracePaste™ Adhesive is intended for use as an orthodontic bonding agent for Metal Brackets, Ceramic Brackets and Buccal Tubes to the tooth’s surface.

Substantial Equivalence Discussion:
The Indications for Use statement for American Orthodontics’ BracePaste™ Adhesive is not identical to the predicate in that the subject device includes the additional indication of bonding of buccal tubes and wording is slightly different; however, the differences do not alter the intended use of the device relative to the predicate. Both devices have the same intended use, to be used as a bonding agent for orthodontic appliances.

Both devices have the same technological characteristics through delivery system, flow behavior, curing mechanism and incorporation of similar materials such as silane treated quartz and silane treated silica, Bis GMA and Bis EMMA, uv light stabilizers and initiators.

The table below outlines the comparisons of the predicate Transbond™ XT and American Orthodontics’ BracePaste™ Adhesive to show substantial equivalency.

<table>
<thead>
<tr>
<th>Device Name / Manufacturer</th>
<th>Transbond™ XT / 3M Unitek</th>
<th>BracePaste™ Adhesive / American Orthodontics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Element</td>
<td>Transbond™ XT / 3M Unitek</td>
<td>BracePaste™ Adhesive / American Orthodontics</td>
</tr>
<tr>
<td>510(k) Number</td>
<td>K880393</td>
<td>K160782</td>
</tr>
<tr>
<td>Classification Code/Regulation Number</td>
<td>DYH 872.3750</td>
<td>DYH 872.3750</td>
</tr>
<tr>
<td>Intended Use</td>
<td>3M Unitek Transbond™ XT is designed for direct bonding of ceramic brackets and metal brackets.</td>
<td>American Orthodontics’ BracePaste™ Adhesive is intended for use as an orthodontic bonding agent for Metal Brackets, Ceramic Brackets, and Buccal Tubes to the tooth’s surface.</td>
</tr>
<tr>
<td>Delivery System</td>
<td>Syringe / Carpule</td>
<td>Syringe / Carpule</td>
</tr>
<tr>
<td>Flow Behavior</td>
<td>Flowable</td>
<td>Flowable</td>
</tr>
<tr>
<td>Curing Mechanism</td>
<td>Orthodontic Curing Light</td>
<td>Orthodontic Curing Light</td>
</tr>
<tr>
<td>Filler Composition</td>
<td>Silane Treated Quartz</td>
<td>Silane Treated Quartz</td>
</tr>
<tr>
<td></td>
<td>Silane Treated Silica</td>
<td>Silane Treated Silica</td>
</tr>
</tbody>
</table>
**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. Biocompatibility/Cytotoxicity according to ISO 10993-5 Biological Evaluation of Medical Devices – Part 5: Tests for In-Vitro Cytotoxicity  
2. Viscosity and Consistency Test  
3. Drift Test  
4. Performance/Shear Bond Strength in accordance to ISO 29022:2013  
5. Compatibility Testing  
7. Density Testing  
8. Compressive Testing  
9. Flexural Strength and Modulus of Elasticity Testing according to ISO 4049:2009 Polymer-Based Restorative Materials  
10. Surface Hardness Testing

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 BracePaste™ Adhesive. Results of bench testing indicate that BracePaste™ Adhesive performs as well as the predicate Transbond™ XT. Any slight differences do not affect the original function or intended purpose of the device.

**Test Method Summary:**

<table>
<thead>
<tr>
<th>Test Method</th>
<th>BracePaste™ Adhesive</th>
<th>Transbond XT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bond Strength on Enamel (24 hrs. in water)</td>
<td>29.66 N/mm²</td>
<td>30.62 N/mm²</td>
</tr>
<tr>
<td>Young’s Modulus</td>
<td>13,766 MPa</td>
<td>16,468 MPa</td>
</tr>
<tr>
<td>Flexural Strength</td>
<td>109 MPa</td>
<td>123 MPa</td>
</tr>
<tr>
<td>Compressive Strength</td>
<td>259 MPa</td>
<td>241 MPa</td>
</tr>
</tbody>
</table>

**Conclusion:**  
BracePaste™ Adhesive has the following similarities to the legally marketed predicate Transbond™ XT (K880393):  
- Same intended use, and  
- Same technological characteristics through delivery system, flow behavior, curing mechanism and incorporation of similar materials.