DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

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,

Susan Runner DDS, MA

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

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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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.

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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.

	Device Name / Manufacturer	
Element	**Transbond™ XT/ 3M Unitek**	**BracePaste™ Adhesive / American Orthodontics**
510(k) Number	K880393	K160782
Classification Code/ Regulation Number	DYH 872.3750	DYH 872.3750
Intended Use	3M Unitek Transbond™ XT is designed for direct bonding of ceramic brackets and metal brackets.	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.
Delivery System	Syringe / Carpule	Syringe / Carpule
Flow Behavior	Flowable	Flowable
Curing Mechanism	Orthodontic Curing Light	Orthodontic Curing Light
Filler Composition	Silane Treated Quartz Silane Treated Silica	Silane Treated Quartz Silane Treated Silica

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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
6. Shear Bond Strength in accordance to DIN 13990-1 (2009) Dentistry – Test Methods for Shear Bond Strength of Adhesives for Orthodontic Attachments – Part 1: Bonding of the Interfacial Surfaces Adhesive-Attachment and Adhesive-Enamel and DIN 13990-2 (2009) Dentistry – Test Methods for Shear Bond Strength of Adhesive for Orthodontic Attachments – Part 2: Bonding of the Entire Bonding System Attachment-Adhesive-Enamel
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:

Test Method	BracePaste™ Adhesive	Transbond XT
Bond Strength on Enamel (24 hrs. in water)	29.66 N/mm^2	30.62 N/mm^2
Young's Modulus	13,766 MPa	16,468 MPa
Flexural Strength	109 MPa	123 MPa
Compressive Strength	259 MPa	241 MPa

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.