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

February 6, 2018

Re: K172953
Trade/Device Name: Acid Etchant
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: Class II
Product Code: KLE
Dated: November 13, 2017
Received: November 16, 2017

Dear Trang 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); 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.

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.

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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mary S. Runner -S

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

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)*
unknown K172953

Device Name
Acid Etchant

Indications for Use *(Describe)*
Acid Etchant is a phosphoric acid etchant used for etching enamel and dentin to promote adhesion of primer/bonding agent adhesives to tooth structure and restorative materials.

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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510(k) Summary

Preparation Date: October 25, 2017

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: Acid Etchant
Common Name: Acid Etchant
Classification Name: Agent, Tooth Bonding, Resin
Product Code: KLE
Regulation Number (21CFR): 872.3200

Predicate Device Information:

Product/Trade Name: E Dental Products e-1 Etchants
Manufacturer: E Dental Products
510(k) #: K152110
Classification Name: Agent, Tooth Bonding, Resin
Product Code: KLE
Regulation Number (21CFR): 872.3200

Description of the Device:

Acid Etchant is a phosphoric acid etchant used for etching enamel and dentin to promote adhesion of primer/bonding agent adhesives to tooth structure and restorative material. The Acid Etchant will be available in gel and liquid form. The gel form will be contained in syringes and the liquid form will be contained in dropper bottles. Applicator tips will be provided with the gel form.

The Acid Etchant contains water, 37% phosphoric acid (CAS# 7664-38-2), silica and green dye. The silica is used as a thickener. The amount of silica will determine the flow behavior and viscosity of the Acid Etchant. The green dye is to provide contrast to the tooth's color. The combination of the flow behavior, delivery system and green dye provides and facilitates accurate and controlled application of the Acid Etchant during orthodontic treatment.

Indications for Use:

Acid Etchant is a phosphoric acid etchant used for etching enamel and dentin to promote adhesion of primer/bonding agent adhesives to tooth structure and restorative materials.

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Substantial Equivalence Discussion:

The Indications for Use statement for American Orthodontics' Acid Etchant is not identical to the predicate in that the subject device includes glass ionomer cements 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 etching agents.

Both devices have the same technological characteristics through delivery system, flow behavior, consistency, % Phosphoric Acid (CAS #: 7664-38-2), pH and incorporation of similar materials.

The table below outlines the comparison of the predicate device, E Dental Products e-1 Etchants and American Orthodontics' Acid Etchant to show substantial equivalency.

	Device Name / Manufacturer	
Element	**PREDICATE** **Device: E Dental Products e-1 Etchants** **Manufacturer: E Dental Products**	**Device: Acid Etchant** **Manufacturer: American Orthodontics**
510(k) Number	K152110	unknown
Classification Code/ Regulation Number	KLE 872.3200	KLE 872.3200
Intended Use	Etch enamel, dentin, and glass ionomer cements.	Acid Etchant is a phosphoric acid etchant used for etching enamel and dentin to promote adhesion of primer/bonding agent adhesives to tooth structure and restorative materials.
Delivery System	Syringe	Syringe/Dropper Bottle
Material Composition	water phosphoric acid silica dye	water phosphoric acid colloidal silica dye
% Phosphoric Acid	37.0%	37.0%
pH	1.6	1.6
Flow Behavior	Viscous	Viscous/Low Viscous
Consistency	Thixotropic Gel	Thixotropic Gel/Thickened Fluid

The biocompatibility of the predicate device (E Dental Products e-1 Etchants: K152110) and American Orthodontics' Acid Etchant is essentially equivalent due to the fact that the chemical composition and properties are the same. Additionally, the original manufacturer's post-market experience has not shown any significant or adverse events. The predicate device (E Dental Products e-1 Etchants: K152110) did not have any reported issues or recalls according to FDA requirements.

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Performance Data:

Clinical Performance Testing
No clinical performance testing has been conducted.

Non-Clinical Performance Testing
The following non-clinical performance tests were conducted:

1. Performance Test in Accordance with ISO 29022:2013
2. Viscosity Testing
3. pH and Acid Content Testing
4. Compatibility 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 Acid Etchant. Results of bench testing indicate that Acid Etchant performs as well as the predicate E Dental Products e-1 Etchants. Any slight differences do not affect the original function or intended purpose of the device.

Test Method Summary:

Device Name:	**Average Bond Strength [N/mm²]**	**Viscosity (Pas):**	**Calculated pH:**	**% Phosphoric Acid:**
Acid Etchant (Gel)	27.20	10.8	1.6	37.5
Acid Etchant (Liquid)	26.91	0.54	1.6	37.6
E Dental Products e-1 Etchants (Predicate)	26.71	7-4.7	1.6	37*

**Stated value from manufacturer*

Compatibility Testing: It was determined that there were no incompatibilities or negative interactions found between the acid etchant and packaging/containers.

Conclusion:

Acid Etchant has the following similarities to the legally marketed predicate E Dental Products e-1 Etchants (K152110):

- Same intended use, and
- Same technological characteristics through delivery system, flow behavior, consistency, % Phosphoric Acid (CAS #: 7664-38-2), pH and incorporation of similar materials.