October 14, 2022

TP Orthodontics, Inc.
Cristiane Muller
Clinical & Regulatory Affairs Manager
100 Center Plaza
La Porte, Indiana 46350-9672

Re: K214054
Trade/Device Name: TP Orthodontics Light-Cure Adhesive System, TP Orthodontics Pre-Applied Adhesive, TP Orthodontics Etchant208520
Regulation Number: 21 CFR 872.3750
Regulation Name: Bracket Adhesive Resin And Tooth Conditioner
Regulatory Class: Class II
Product Code: DYH, KLE
Dated: September 7, 2022
Received: September 16, 2022

Dear Cristiane Muller:

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,

For Michael E. Adjodha, M. ChE.
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: 0MB No. 0910-0120
Expiration Date: 06/30/2023
See *PRA Statement below.*

510(k) Number *(if known)*
K214054

Device Name
TP Orthodontics Light Cure Adhesive System, TP Orthodontics Pre-Applied Adhesive and TP Orthodontics Etchant

Indications for Use *(Describe)*

TP Orthodontics Light Cure Adhesive System is indicated for use as an orthodontic bonding agent for metal brackets, ceramic brackets, and buccal tubes to the tooth's surface.

TP Orthodontics Pre-Applied Adhesive is indicated for use in orthodontic appliance application and bonding for orthodontic treatment.

TP Orthodontics Echant is indicated 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)*

X 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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September 7, 2022

510(k) Summary - K214054

Submitter Information

TP Orthodontics, Inc.
100 Center Plaza, La Porte, IN 46350-9672
Contact Person: Cristiane Muller
Phone Number: 219.785.2591
Fax: 219.324.3029
E-mail: regulatory@tportho.com

Device Information

Trade Name: TP Orthodontics Light Cure Adhesive System, TP Orthodontics Pre-Applied Adhesive and TP Orthodontics Etchant
Common Name: Adhesive, Bracket and Tooth Conditioner, Resin
Product Code: DYH
Classification Name: Bracket Adhesive Resin and Tooth Conditioner
Regulation Number: 872-3750
Device Class: II
Classification Panel: Dental

Primary Predicate Device

Device	Applicant	510(k) Number
BracePaste Adhesive	American Orthodontics	K160782

Secondary Predicate Devices

Device	Applicant	510(k) Number
APC Plus Adhesive	3M Unitek Corp.	K020394
Acid Etchant	American Orthodontics	K172953

Reference Predicate Devices

Device	Applicant	510(k) Number
Transbond XT Light Cured Orthodontic Adhesive/ Transbond XT Primer	Unitek Corp.	K880393
APC Flash-Free Adhesive	Unitek Corp.	K113197

Indications for Use

TP Orthodontics Light Cure Adhesive System is indicated for use as an orthodontic bonding agent for metal brackets, ceramic brackets, and buccal tubes to the tooth's surface.

TP Orthodontics Pre-Applied Adhesive is indicated use in orthodontic appliance application and bonding for orthodontic treatment.

TP Orthodontics Acid Etchant is indicated for etching enamel and dentin to promote adhesion of primer/bonding agent adhesives to tooth structure and restorative materials.

Device Description and Summary of Technological Characteristics

TP Orthodontics Light Cure Adhesive System and TP Orthodontics Pre-Applied Adhesive are light cure orthodontic adhesive used for bonding the orthodontic brackets, molar tubes, and buccal tubes to the surface of teeth for orthodontic treatment. The variations available are:

- TP Orthodontics Light Cure Adhesive System, which consists of an adhesive paste (will be available in a pre-loaded syringe), and sealant.
- TP Orthodontics Pre-Applied Adhesive, consisting of bracket adhesive pre-applied to the bracket pad.

The adhesives prevent bracket drift during placement, and is easy to clean-up excess ('flash') prior to curing. The adhesive is polymerized ('cured') by exposure to a dental curing light, and once cured it creates a bond, attaching the orthodontic appliance to the teeth.

TP Orthodontics Etchant is a phosphoric acid etchant used on tooth enamel or dentin in preparation for orthodontic bonding. It is a blue gel and will be contained in a syringe, which will use disposable dispensing tips for its controlled application.

Table 5.1. Substantial Equivalence Comparison

Characteristic	TP Orthodontics Light Cure Adhesive System	BracePaste	Transbond XT (Light Cured Orthodontic Adhesive/ Primer)
Device	**Proposed Device**	**Predicate Device**	**Reference Predicate**
510(k)	To be determined	K160782	K880393
Manufacturer	TP Orthodontics, Inc.	American Orthodontics	Unitek Corp.
Regulation Number	21 CFR 872.3750	21 CFR 872.3750	21 CFR 872.3750
Device Classification Name	Bracket Adhesive Resin and Tooth Conditioner	Bracket Adhesive Resin and Tooth Conditioner	Bracket Adhesive Resin and Tooth Conditioner
Product Code	DYH	DYH	DYH
Device Class	Class II	Class II	Class II
Indications for Use	Indicated for use as an orthodontic bonding agent for metal brackets, ceramic brackets, and buccal tubes to the tooth's surface.	Intended for use as an orthodontic bonding agent for Metal Brackets, Ceramic Brackets and Buccal Tubes to the tooth's surface.	Designed for direct bonding of ceramic orthodontic brackets and metal brackets.
Dentition to be Used	Mixed and Permanent	Mixed and Permanent	Mixed and Permanent
Parts that can be Bonded	Fixed orthodontic appliance (Brackets, Tubes, Accessories).	Fixed orthodontic appliance (Brackets, Tubes, Accessories).	Fixed orthodontic appliance (Brackets, Tubes, Accessories).
Mode of Use	Light Cure orthodontic adhesive intended for use in bonding appliances for orthodontic treatment. Adhesive is applied to appliance. Once part is positioned, visible light is used for curing the adhesive and by this affix part to tooth.	Light Cure orthodontic adhesive intended for use in bonding appliances for orthodontic treatment. Adhesive is applied to appliance. Once part is positioned, visible light is used for curing the adhesive and by this affix part to tooth.	Light Cure orthodontic adhesive intended for use in bonding appliances for orthodontic treatment. Adhesive is applied to appliance. Once part is positioned, visible light is used for curing the adhesive and by this affix part to tooth.
Components	Paste and Sealant (primer)	Paste	Paste and Sealant (primer)
Delivery System	Syringe (paste) and bottle with dropper (sealant)	Syringe/ Carpule	Syringe/ Carpule (paste) and bottle with dropper (sealant)
Curing Mechanism	Orthodontic Curing Light	Orthodontic Curing Light	Orthodontic Curing Light
Curing Recommendations	IFU recommends following curing light manufacturer's directions. Instructions are provided if using a 300mW/cm^2 and average wavelength of 400-500nm curing light	IFU recommends following curing light manufacturer's directions. Instructions are provided if using Blu Ray 3 (3000 mW/cm^2), which is distributed by American Orthodontics	IFU recommends following curing light manufacturer's directions. Instructions are provided if using 3M's Ortholux Luminous Curing Light (1600 mW/cm^2)
Resin Base	Methacrylate Monomers	Methacrylate Monomers	Methacrylate Monomers
Filler Composition (paste)	Silane treated silica and silane treated glass	Silane treated silica and silane treated glass (aluminum boron silicate glass)	Silica and Quartz
Catalyst	Camphoroquinone	Camphoroquinone	Camphoroquinone
Prescription (Rx) or Over-the-Counter (OTC)	Rx	Rx	Rx

Table 5.2. TP Orthodontics Adhesive Comparison – TPO® Pre-Applied Adhesive

Characteristic	TP Orthodontics Pre-Applied Adhesive	APC Plus Adhesive
Device	**Proposed Device**	**Predicate Device**
510(k)	To be determined	K020394
Manufacturer	TP Orthodontics, Inc.	3M Unitek Corp.
Regulation Number	21 CFR 872.3750	21 CFR 872.3750
Device Classification Name	Bracket Adhesive Resin and Tooth Conditioner	Bracket Adhesive Resin and Tooth Conditioner
Product Code	DYH	DYH, EJF, DYW
Device Class	Class II	Class II
Indications for Use	Indicated for use in orthodontic appliance application and bonding for orthodontic treatment.	Indicated for use in orthodontic appliance application and bonding for orthodontic treatment.
Dentition to be Used	Mixed and Permanent	Mixed and Permanent
Bracket Types	TP Orthodontics commercially available metal and ceramic brackets.	Unitek commercially available metal and ceramic brackets.
Mode of Use	Light Cure orthodontic adhesive intended for use in bonding appliances for orthodontic treatment. Adhesive is already pre-applied to appliance. Once part is positioned, visible light is used for curing the adhesive and by this affix part to tooth.	Light Cure orthodontic adhesive intended for use in bonding appliances for orthodontic treatment. Adhesive is already pre-applied to appliance. Once part is positioned, visible light is used for curing the adhesive and by this affix part to tooth
Delivery System	Pre-applied	Pre-applied
Curing Mechanism	Orthodontic Curing Light	Orthodontic Curing Light
Curing Recommendations	IFU recommends following curing light manufacturer's directions. Instructions are provided if using a 300mW/cm2 and average wavelength of 400-500nm curing light	IFU recommends following curing light manufacturer's directions. Instructions are provided if using 3M's Ortholux Luminous Curing Light (1600 mW/cm^2)
Resin Base	Methacrylate Monomers	Methacrylate Monomers
Filler Composition	Silica and Glass	Silica, Glass and Quartz.
Catalyst	Camphoroquinone	Camphoroquinone
Prescription (Rx) or Over-the-Counter (OTC)	Rx	Rx

Table 5.3. TP Orthodontics Adhesive Comparison – TPO Enamel Etchant

Characteristic	TP Orthodontics Etchant	Acid Etchant
Device	**Proposed Device**	**Predicate Device**
510(k)	To be determined	K172953
Manufacturer	TP Orthodontics, Inc.	American Orthodontics
Regulation Number	21 CFR 872.3750	21 CFR 872.3200
Device Classification Name	Bracket Adhesive Resin and Tooth Conditioner	Agent, tooth bonding, resin
Product Code	DYH, KLE	KLE
Device Class	Class II	Class II
Indications for Use	TP Orthodontics Etchant is indicated for etching enamel and dentin to promote adhesion of primer/bonding agent adhesives to tooth structure and restorative materials.	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.
Dentition to be Used	Mixed and Permanent	Mixed and Permanent
Mode of Use	Applied to tooth surface to prepare it for orthodontic bonding.	Applied to tooth surface to prepare it for orthodontic bonding.
Delivery System	Syringe	Syringe
% Phosphoric Acid	37% (CAS 7664-38-2)	37% (CAS 7664-38-2)
Material Composition	Water, phosphoric acid, silica, dye	Water, phosphoric acid, silica, dye
Consistency	Thixotropic Gel/Thickened Fluid	Thixotropic Gel/Thickened Fluid
Prescription (Rx) or Over-the-Counter (OTC)	Rx	Rx

Clinical Performance Testing

No clinical performance testing was conducted on TP Orthodontics Light Cure Adhesive System, TP Orthodontics Pre-Applied Adhesive, and TP Orthodontics Etchant.

Non-Clinical Performance Testing

TP Orthodontics Light Cure Adhesive System, TP Orthodontics Pre-Applied Adhesive and TP Orthodontics Etchant bench testing was performed. The proposed device passed testing and performed similar to its predicate devices (test reports are attached to this submission).

Biocompatibility Testing

Biocompatibility testing TP Orthodontics Light Cure Adhesive System and TP Orthodontics Pre-Applied Adhesive was performed per guidance “Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" as discussed in the Biocompatibility section of this application.

TP Orthodontics Etchant and the predicate device (American Orthodontics’ Acid Etchant) have similar chemical composition, properties and utilize phosphoric acid CAS# 7664-38-2. The biocompatibility of these devices is equivalent; therefore, biocompatibility testing of

TP Orthodontics Etchant was not performed.

Substantial Equivalence Conclusion

TP Orthodontics Light Cure Adhesive System and TP Orthodontics Pre-Applied Adhesive present substantially equivalent indication for use, technological characteristics, mechanism of action, composition, and biocompatibility as its predicate devices. There are slight differences in the language of the instructions for use, however these differences do not impact safety and efficacy of the device. *TP Orthodontics Light Cure Adhesive System* has similar components as its reference predicate device, being comprised of an adhesive paste and liquid sealant/ primer.

TP Orthodontics Etchant presents substantially equivalent indication for use, technological characteristics, mechanism of action, composition, and biocompatibility as its predicate devices. It is concluded that TP Orthodontics Light Cure Adhesive System, TP Orthodontics Pre-Applied Adhesive and TP Orthodontics Etchant are substantially equivalent to their predicate devices.