July 8, 2021

Reliance Orthodontic Products, Inc
Brian Dean
Biomedical Engineering Consultant
Cook Device Solutions
7640 Delaine Ct
Indianapolis, Indiana 46254

Re: K210945
Trade/Device Name: Ultra SEP
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: Class II
Product Code: KLE
Dated: May 12, 2021
Received: May 13, 2021

Dear Brian Dean:

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K210945

Device Name
Ultra SEP

Indications for Use *(Describe)*

Ultra SEP is a self etching primer intended to be used for the preparation of an enamel surface prior to bonding with a light cure orthodontic adhesive.

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.

K210945

RELIANCE ORTHODONTIC PRODUCTS

Reliance Orthodontic Products Inc. 1540 West Thorndale Ave. Itasca, IL 60143 USA
Phone: (630) 773-4009 | Website: www.relianceorthodontics.com

Submitter Information:

Date of 510(k) Summary: 3/19/2021
Submitter: Reliance Orthodontics Products Inc.
Preparer and Contact Name: Brian Dean, BME Consultant Email: bdean@cookds.com
510(k) Owner: Paul Gange, President Email: pgange@relianceorthodontics.com
Address: 1540 West Thorndale Ave. Itasca, IL 60143 USA
Phone: 630-773-4009 / Fax: 630-250-7704

Device Name and Classification:

Common Name of Device:	Self Etching Primer
Device Proprietary Name:	Ultra SEP
Classification Panel:	Dental
Classification Number:	872.3200
Classification Name:	Resin Tooth Bonding Agent
Class:	II
Product Code:	KLE

Substantial Equivalence:

Legally marketed devices to with equivalence is claimed:

- 3M Unitek Transbond™ Plus Self Etching Primer 510(k) (Submitted to FDA as K984246 – Prompt L-Pop by Espe Dental AG)

Device Description

Ultra SEP is a self etching primer which can etch up to 6 teeth with a single drop. The material is dispensed from a bottle into a light impervious mixing well, and transferred to teeth by a saturated microbrush. Ultra SEP creates an ideal surface for a light cure paste to adhere teeth and brackets for orthodontic treatment.

Ultra SEP is used in combination with a light impervious mixing well (SEPW) and microbrushes (MB).

Indications for Use and Population:

Intended Use: Ultra SEP is a self etching primer intended to be used for the preparation of an enamel surface prior to bonding with a light cure orthodontic adhesive.

Diseases/Conditions for diagnosis, treatment, prevention, cure, or mitigation: None

Population: Adults and Pediatrics. Orthodontic or Dental Office professional use.

Predicate Device:

- 3M Unitek Transbond™ Plus Self Etching Primer 510(k) K984246 dated 11/17/1998 is similar in intended use, handling and technology compared to the device described in this submission; this 3M product is considered the primary predicate.
- Reliance S.E.P. 510(k) K071688 dated 08/24/2007 is similar in intended use, handling and technology compared to the device described in this submission; this Reliance Orthodontics product is considered a reference.

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Comparison of Technological Characteristics with the Predicate Device:

Submission	**Reliance Orthodontics Ultra SEP**	**3M Unitek Transbond™ Plus Self Etching Primer**	**Reliance Orthodontics S.E.P.**
Classification	Class II, KLE, 21CFR872.3200	Class II, KLE, 21CFR872.3200	Class II, KLE, 21CFR872.3200
Intended Use	Self Etching Primer, Single Step Delivery for use with light cure bonding orthodontic adhesives	Self Etching Primer, Single Step Delivery for use with light cure bonding orthodontic adhesives	Self Etching Primer, Single Step Delivery for use with light cure bonding orthodontic adhesives
Device Description	• Combines etching and priming in one easy step • Effective bond strength	• Combines etching and priming in one easy step • Effective bond strength	• Combines etching and priming in one easy step • Effective bond strength
Chemical Composition	Acidic Monomer / Solvent	Acidic Monomer / Solvent	Acidic Monomer / Solvent
Dispensing	Boston Round Bottle with Dropper Cap	A single-patient use foil pack contains pre-measured etchant and light cure primer.	A multi-patient use hand-held dispenser with SEP filled cartridge.
Sterilization	Non-Sterile	Non-Sterile	Non-Sterile

Non-Clinical Data Submitted

Shear bond strength testing comparisons conducted between the Reliance Orthodontics Ultra SEP, the predicate device 3M Unitek Transbond™ Plus Self Etching Primer, and the reference Reliance Orthodontics S.E.P. demonstrate that the applicant device is equivalent to the legally marketed device in terms of effectiveness.

Additionally, toxicity testing was conducted using an Oral Toxicity Test method and was found to be non toxic.

Conclusions

Clinical testing was determined to be unnecessary with the approval of all non-clinical testing, based on the nonclinical testing conducted and equivalency in characteristics demonstrated between Reliance Ultra SEP and 3M Unitek Transbond™ Plus Self Etching Primer devices. In conjunction with biocompatibility demonstrated via ISO 7405 and ISO 10993-5 evaluations, evidence has been submitted to demonstrate Reliance Ultra SEP is safe and equivalent to or better than the 3M Unitek Transbond™ Plus Self Etching Primer (K984246) device in terms of performance as an Orthodontic Self Etching Primer.