K071688

Reliance Orthodontic Products, Inc.

Toll Free 1-800-323-4348 · Phone 630-773-4009 · Fax 630-250-7704
PO Box 678 · Itasca, IL · 60143 · U.S.A.

SEP - 7 2007

Section 5.0
510 (k) Summary

Note: This summary is provided in accordance with the requirements of 21CFR807.92 (c).

510 (k) Owners Name:	Reliance Orthodontic Products, Inc. Paul Gange, President
Address:	1540 West Thorndale Avenue Itasca, Il 60143 USA
Phone Number:	630-773-4009
Fax Number:	630-250-7704
Contact Person:	Paula Wendland, Regulatory Affairs Manager (Preparer)

Date 510 (k) Summary was Prepared: June 14, 2007

Medical Device Name:

- Trade name – Reliance S.E.P.
- Common name – Self Etching Primer
- Classification name – Resin Tooth Bonding Agent (21CFR872.3200, Product Code KLE, Class II Device)

LEGALLY MARKETED DEVICE TO WHICH EQUIVALENCE IS CLAIMED (PREDICATE DEVICE) [807.92(a) (3)]:

- 3M Unitek Transbond ™ Plus Self Etching Primer (510(k) submission K984246 under the ESPE Dental Ag Prompt L-Pop)

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DESCRIPTION OF THE APPLICANTS DEVICE:

The Reliance S.E.P. is a one step self etching primer contained in a hand-held dispenser. Upon manual compression into a light impervious mixing well, enough solution is dispensed to prepare the enamel surface of up to 20 teeth.

INTENDED USE AND POPULATION:

The Reliance S.E.P. is a one step self etching primer intended to be used for the preparation of a tooth surface prior to bonding an orthodontic appliance(s) with a light cure adhesive. The intended patient population ranges from pediatric to adult recipients of orthodontic treatment.

TECHNOLOGICAL AND PERFORMANCE CHARACTERISTICS:

Performance Characteristics of the Reliance S.E.P. versus the 3M Unitek Transbond ™ Plus Self Etching Primer:

Property	Reliance S.E.P.	3M Unitek Transbond™ Plus Self Etching Primer
Intended Use	Self Etching Primer, Single Step Delivery for use with light cure bonding orthodontic adhesives	Self Etching Primer, Single Step Delivery use with light cure bonding orthodontic adhesives.
Mechanical / Physical Properties	• 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

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Shear bond strength testing comparisons conducted between the Reliance S.E.P. and the predicate device, 3M Unitek Transbond ™ Plus Self Etching Primer 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. Sufficient data has been generated to demonstrate that the applicant device is safe for its intended use.

Paula Wendland
Regulatory Affairs Manager
Reliance Orthodontic Products, Inc.
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Fax: 630-250-7704

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 7 2007

Ms. Paula Wendland
Regulatory Affairs Manager
Reliance Orthodontic Products, Incorporated
1540 West Thorndale Avenue
Itasca, Illinois 60143

Re: K071688
Trade/Device Name: Reliance S.E.P.
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: II
Product Code: KLE
Dated: August 24, 2007
Received: August 27, 2007

Dear Ms. Wendland:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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SECTION 6.0 INDICATIONS FOR USE STATEMENT

Indications for Use

510(k) Number (if known): K071688

Device Name: Reliance S.E.P.

Indications for Use:

The Reliance S.E.P. is a one step self etching primer intended to be used for the preparation of a tooth surface prior to bonding an orthodontic appliance(s) with a light cure adhesive.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K071688