K123348

Reliance Orthodontic Products, Inc.

Toll Free 1-800-323-4348 · Phone 630-773-4009 · Fax 630-250-7704
1540 West Thorndale Ave. · Itasca, IL · 60143 · U.S.A.

FEB 2 8 2013

Section 5.0 510 (k) Summary

Note: This summary is provided in accordance with 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: August 13, 2012

Medical Device Name:

- Trade name – Clear Aligner Adhesive
- Common name – Light Cure Orthodontic Adhesive for Aligners
- Classification name – Bracket Adhesive Resin and Tooth Conditioner (21CFR872.3750, Product Code DYH, Class II Device)

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

- Flowtain™ with Reliance Orthodontic Products, Inc. and Plastic Conditioner : 510(K083051 and K880792, respectively).

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5.1 DESCRIPTION OF THE APPLICANTS DEVICE:

The Clear Aligner Adhesive is a light cure, orthodontic adhesive for metal, composite and porcelain brackets and appliances to bond to a thermoplastic aligner. The Clear Aligner Adhesive is formulated in a viscosity that flows easily from the syringe and bonds chemically to a typically difficult to adhere to surface, a thermoplastic aligner now common in the dental industry. This adhesive, upon polymerization, is clear and virtually indistinguishable from the thermoplastic aligner thereby making it aesthetically pleasing to the patient.
The light cure property of the adhesive allows the user to determine the polymerization time required by simply exposing the adhesive to an LED light source until set.

The Clear Aligner Adhesive will be marketed in a push syringe for dispensing.

5.2 INTENDED USE AND POPULATION:

The Clear Aligner Adhesive is intended for use as an orthodontic bonding adhesive for brackets and appliances to thermoplastic aligner surfaces.

5.3 PREDICATE DEVICE:

Reliance Orthodontic Products, Inc. Flowtain and Plastic Conditioner, 510(k) submission (K083051 and 880792, respectively) dated 2/20/2009 and 1/15/1988. *Flowtain and Plastic Conditioner are similar in intended use for bonding to* thermoplastic aligners. Flowtain is similar in compositional basis to the Clear Aligner Adhesive.

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5.4 TECHNOLOGICAL AND PERFORMANCE CHARACTERISTICS:

Performance Characteristics of CLEAR ALIGNER ADHESIVE versus Flowtain with Plastic Conditioner:

Property	**Clear Aligner Adhesive**	**Reliance Orthodontic Products, Inc. Flowtain with Plastic Conditioner**
Intended Use	**Orthodontic Bonding Adhesive for Thermoplastic Aligners**	**Orthodontic Bonding Adhesive for retention of Thermoplastic Aligners**
Method of Cure	**Light Cure**	**Light Cure**
Aesthetic Features	**Clear when polymerized**	**Shade A1 when polymerized**
Physical Properties	**Chemical bond to thermoplastic aligner and metal, composite or porcelain**	**Mechanical and Chemical bond to thermoplastic aligner, enamel, metal, composite and porcelain**

5.5 Summary:

Clear Aligner Adhesive was tested and compared to Reliance Orthodontic Products, Inc. *Flowtain in conjunction with Plastic Conditioner for Shear Bond* Strength. Testing resulted in highly increased bond strength values for the Clear Aligner adhesive when compared to the use of Flowtain with a Plastic conditioner.

Clear Aligner Adhesive has been tested for cytotoxicity via the ISO 10993-5 elution test method and showed no evidence of causing cell lysis or toxicity.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 28, 2013

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

Re: K123348
Trade/Device Name: Clear Aligner Adhesive
Regulation Number: 21 CFR 872.3750
Regulation Name: Bracket Adhesive Resin and Tooth Conditioner
Regulatory Class: II
Product Code: DYH
Dated: January 3, 2013
Received: January 24, 2013

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. 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Kwame O. Ulmer for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, 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): K123348

Device Name: _____ CLEAR ALIGNER ADHESIVE _____

Indications for Use:

The CLEAR ALIGNER ADHESIVE is intended for use as an orthodontic bonding adhesive for brackets and appliances to thermoplastic aligner surfaces.

Prescription Use __X_____ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

Susan Runner, DDS, MA Mary S. Runner -S 2013.02.27 13:29:06 -05'00'

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

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