



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

Reliance Orthodontic Products Inc.
Paula Wendland
Regulatory Affairs Manager
1540 West Thorndale Ave
Itasca, Illinois 60143

October 6, 2016

Re: K161684

Trade/Device Name: Quantum LB
Regulation Number: 21 CFR 872.3750
Regulation Name: Bracket Adhesive Resin And Tooth Conditioner
Regulatory Class: Class II
Product Code: DYH
Dated: June 15, 2016
Received: June 17, 2016

Dear Paula 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 contact the Division of Industry and Consumer Education 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>. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education 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,

A handwritten signature in black ink that reads "Susan Runno DDS, MA". The signature is written in a cursive style. A large, semi-transparent "FDA" watermark is visible behind the signature.

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



Reliance Orthodontic Products, Inc.

Toll Free 1-800-323-4348 · Phone 630-773-4009 · Fax 630-250-7704
P.O. Box 678, 1540 West Thorndale Ave. · Itasca, IL · 60143 · U.S.A.

SECTION 6.0 INDICATIONS FOR USE STATEMENT

Indications for Use

510(k) Number (if known): K161684

Device Name: Quantum LB

Indications for Use:

This Device is intended for use as a light cure, orthodontic adhesive.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

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



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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/Owner

Address: 1540 West Thorndale Ave.
 Itasca, IL 60143 USA

Contact Phone Number: 630-773-4009
Fax Number: 630-250-7704

Contact Person: Paula Wendland, Regulatory Affairs Manager

Date 510(k) Summary was Prepared: May 31st, 2016

Medical Device Name:

- Trade name – Quantum LB
- Common name – Orthodontic Bracket Adhesive
- Classification name – Adhesive, Bracket and Tooth Conditioner, Resin (21CFR872.3750, Product Code DYH, Class II Device)

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

- Transbond XT 510(k) K880393



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5.1 DESCRIPTION OF THE APPLICANTS DEVICE:

This device is a light-cure orthodontic adhesive intended for bonding brackets and appliances to a tooth surface. This device will bond to any enamel, porcelain, composite or metal tooth surface that has been properly conditioned.

This device will be available in push syringe or tips for preferences in dispensing.

5.2 INTENDED USE AND POPULATION:

This device is intended for use as a light cure, orthodontic adhesive.

5.3 PREDICATE DEVICE:

3M Unitek Transbond XT, 510(k) submission (K880393) dated 3/31/1998 is similar in intended use, handling and technology compared to the device described in this submission.

5.4 TECHNOLOGICAL AND PERFORMANCE CHARACTERISTICS:

Performance Characteristics of the QUANTUM LB versus TRANSBOND XT:

Property	QUANTUM LB	TRANSBOND XT
Intended Use	Light Cure Orthodontic Adhesive	Light Cure Orthodontic Adhesive
Composition	Methacrylate Monomer	Methacrylate Monomer
Product Features	Bonds to conditioned Enamel, Composite, Porcelain and Metal tooth surfaces.	Bonds to conditioned Enamel, Porcelain and Metal tooth surfaces.
Dispensing Method	Push Syringe and Tips	Push Syringe and Tips
Method of Cure	Light Cure	Light Cure

5.5 Summary:

The Quantum LB was tested against Transbond™ XT using in-vivo performance test method for shear bond strength. Testing resulted in similar performance between the two adhesives.



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A biocompatibility evaluation was conducted per ISO10993 for the composition of the Quantum LB device and determined to not directly or through the release of material constituents produce adverse local or systemic effects.

In addition, Cytotoxicity testing was conducted on Quantum LB using the ISO 10993-5 Elution Method. The Quantum LB was evaluated for potential cytotoxic effects using an in vitro mammalian cell culture test following the guidelines of ISO10993-5, Biological evaluation of medical device - Part 5: Tests for in vitro cytotoxicity. The Quantum LB showed no evidence of causing cell lysis or toxicity and met the requirements of the test with a grade of less than grade 2 (Mild reactivity).

Quilman 10-6-16