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.

JUL 3 1 2007

K071590

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: June 4, 2007

Medical Device Name:

- Trade name – Therma-Cure™
- Common name – Heat Curable Orthodontic Adhesive
- 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)]:

- Reliance Orthodontic Products, Inc. Light Bond™ Orthodontic Adhesive

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5.1 DESCRIPTION OF THE APPLICANTS DEVICE:

Therma-Cure™ is a heat curable orthodontic adhesive used for the indirect bonding of orthodontic brackets and appliances.

5.2 INTENDED USE AND POPULATION:

Therma-Cure is a heat cure orthodontic adhesive intended to be used within an orthodontic, dental or pediatric dental office for the indirect bonding of orthodontic brackets and appliances. The intended patient population ranges from pediatric to adult recipients of orthodontic treatment.

5.3 PREDICATE DEVICE:

Reliance Orthodontic Products Inc. Light Bond™ Orthodontic Adhesive System, 510(k) submission (K880793) dated June 13, 1988.

5.4 TECHNOLOGICAL AND PERFORMANCE CHARACTERISTICS:

Performance Characteristics of Therma-Cure versus Light Bond:

Property	**Therma-Cure**	**Light Bond**
Intended Use	**Heat Cure adhesive for indirect bonding**	**Light Cure Adhesive for indirect bonding**
Mechanical / Physical Properties	**Single paste in a hand-held delivery**	**Single paste in a hand-held delivery**
Chemical Composition	**Bisphenol A Diglycidyl Methacrylate resin Monomer and Silica Filler Triethyleneglycol Dimethacrylate Diluent 2-3-Di-tert-butyl-4-methylphenol Inhibitor**	**Bisphenol A Diglycidyl Methacrylate / Urethane Dimethacrylate Resin Monomer and Silica Filler Triethyleneglycol Dimethacrylate Diluent 2-3-Di-tert-butyl-4-methylphenol Inhibitor**

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5.5 Summary:

Therma-Cure was tested against Light Bond using in-vivo performance test method for shear bond strength. Testing was conducted using indirect bonding procedure in replicates of 5 for both Therma-Cure and Light Bond, the predicate device. Testing resulted in similar performance between the two adhesives.

Therma-Cure has been proven to be non-toxic when tested according to ISO 10993-5.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 31 2007

Mr. Paul Gange
Regulatory Affairs Manager
Reliance Orthodontic Products, Incorporated
1540 West Thorndale Avenue
Itasca, Illinois 60143

Re: K071590
Trade/Device Name: Therma Cure
Regulation Number: 872.3750
Regulation Name: Bracket Adhesive Resin and Tooth Conditioner
Regulatory Class: II
Product Code: DYH
Dated: June 4, 2007
Received: June 12, 2007

Dear Mr. Gange:

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.

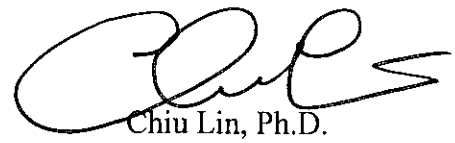
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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): K071590

Device Name: Therma-Cure

Indications for Use:

Therma-Cure is a heat cure orthodontic adhesive intended to be used within an orthodontic, dental or pediatric dental office for the indirect bonding of orthodontic brackets and appliances.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

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

K S Beer DDS for Dr. Susan Runner
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K071590