K094006

Section 5

MAR 23 2010

Traditional 510(k) Summary

This summary of the Traditional 510(k) substantial equivalence information is being submitted in accordance with the requirements of 21 CFR 807 .92.

Applicant's Name and Address

Opal Orthodontics by Ultradent Products Inc.
505 West 10200 South
South Jordan, UT 84095

Contact Person:	Diane Rogers
Title:	Regulatory Affairs Manager
Telephone:	800-552-5512 x4491, 801-553-4491
FAX:	801-553-4609
Date Summary Prepared:	December 23, 2009

Name of the Device

Trade Name:	Opal® Bond MV
Common Name:	Bracket Adhesive Resin and Tooth Conditioner
Device Classification:	II
Classification Product Code:	DYH

Legally Marketed Predicate Devices to Which Equivalence is Claimed

The predicate device is: Opal Bond (K071055). This device is manufactured and distributed by Opal Orthodontics by Ultradent Products, Inc., 505 West, 10200 South, South Jordan,Utah 84095. The Indications for Use have been changed.

Opal® Bond MV is also very similar to one of our competitor's products namely: 3M Unitek Transbond (K073609) Both products are used to adhere brackets and bondable appliances to etched enamel.

Substantial equivalence: Opal® Bond MV formula is similar to Ultradent's Opal Bond (K071055) formula.

Opal® Bond MV is also very similar to one of our competitor's products namely: 3M Unitek's Transbond (K073697).

A comparison of the three products to determine substantial equivalence:

Product	510(k) number	Classification name	Indications for Use
Opal Bond MV	New	Adhesive, Bracket and Tooth Conditioner	Light cure orthodontic adhesive designed for bonding brackets and other bondable appliances to etched enamel.
Opal Bond	K071055	Adhesive, Bracket and Tooth Conditioner	...This system is a bondable device for fixed attached orthodontics
Transbond	K073698	Adhesive, Bracket and Tooth Conditioner	Transbond XT Light Cure Orthodontic Adhesive is designed for bonding ceramic and metal orthodontic brackets.

Indications for Use

Opal® Bond MV is a light cure orthodontic adhesive designed for bonding brackets and other bondable appliances to etched enamel.

Brief Description of Testing Performed

The following tests were conducted during the R & D phase on Opal® Bond MV and compared to 3M Unitek's Transbond (K073697).

a. Shear Peel
b. Flexural Strength
c. Hardness
d. Shear Bond with bracket
e. Compressives
f. Metal Shear
g. Depth of Cure
h. Tensile Pull (lbf)
i. Ambient Light Sensitivity
j. Clinic
k. Lab

Clinical Summary

A detailed Clinical Summary is included in this submission. It contains literature which we have selected that supports our claims for the safety and efficacy of Opal® Bond MV.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Ultradent Products, Incorporated
C/O Ms. Diane Rogers
Regulatory Affairs Manager
Opal Orthodontics
505 West 10200 South
South Jordan, Utah 84095

MAR 23 2010

Re: K094006
Trade/Device Name: Opal® Bond MV
Regulation Number: 21CFR 872.3750
Regulation Name: Bracket Adhesive Resin and Tooth Conditioner
Regulatory Class: II
Product Code: DYH
Dated: December 24, 2010
Received: December 28, 2010

Dear Ms. Rogers:

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,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number (if known): K094006

Device Name: Opal® Bond MV

Indications for Use:

Opal® Bond MV is a light cure orthodontic adhesive designed for bonding brackets and other bondable appliances to etched enamel.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

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

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

R S Betz DDS for Dr. K. P. Mudry

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

510(k) Number: K094006

(Posted November 13, 2003)