JUL 1 6 2010

K100752

TRADITIONAL 510(K) PREMARKET SUMMARY

Peak™ Universal Bond

This summary of the Traditional 510(k) substantial equivalence information is being submitted in accordance with the requirements of 21 CFR 807 for Peak™ Universal Bond.

Applicant's Name and Address

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:	March 3, 2010

Name of the Device

Trade Name:	Peak™ Universal Bond
Common Name:	Agent, Tooth bonding, Resin
Device Classification:	II
Classification Product Code:	KLE

Legally Marketed Predicate Device to Which Equivalence is Claimed

The first predicate device is: Peak™ Bond (K063557). This device is manufactured and distributed by Ultradent Products, Inc., 505 West, 10200 South, South Jordan, Utah 84095. Peak Bond and Peak Universal Bond are exactly the same product with only the addition of 0.2 Chlorhexidine Diacetate. The second predicate device is Premier NexTemp (K051866) manufactured and distributed by Premier Dental Products, 1710 Romano Drive, Plymouth meeting, PA 19462.

Product Description: Peak™ Universal Bond is a single syringe delivered resin bond. It can be used with **Peak™ SE** or with a total etch. It is 7.5% filled with an ethyl alcohol solvent carrier and will cure with most high intensity lights including LEDs. Chlorhexidine is used to ensure long term bond strengths.

Indications for Use: Use for virtually all etching and bonding needs in restorative dentistry for dental patients of all ages.

Peak™ Universal Bond bonds to the following materials:

- Dentin and enamel
- Porcelain
- Metal
- Composite

Comparison Table

	Peak™ Universal Bond (K100752)	Peak™ Bond (K063557)	Premier NexTemp (K051866)
Indications For Use	Use for virtually all etching and bonding needs in restorative dentistry. Peak™ Universal Bond bonds to the following materials: • Dentin and enamel • Porcelain • Metal • Composite	Use for virtually all etching and bonding needs in restorative dentistry. Peak™ Bond bonds to the following materials: • Dentin and enamel • Porcelain • Metal • Composite	Non-eugenol resin-matrix formulation to combine the multiple benefits of fluoride release to protect tooth structure, potassium nitrate for patient comfort and chlorhexidine as an anti-bacterial agent.
Delivery System	Syringe	Syringe	Syringe

Technological Characteristics:

Peak™ Universal Bond is a single syringe delivered resin bond. It can be used with Peak™ SE or with a total etch. It is 7.5% filled with an ethyl alcohol solvent carrier and will cure with most high intensity lights including LEDs. Chlorhexidine is used to ensure long term bond strengths. Both devices have the same technological characteristics before the addition of chlorhexidine. New characteristics are added to enhance the length of the bond strength in Peak Universal Bond.

The purpose of this Traditional 510(k) is to inform the FDA of our intent to market a new product, Peak™ Universal Bond. This product can be used for dental patients of all ages. Peak™ Bond (K063557) and Premier NexTemp (K051866) are our predicates. The formula has been modified as follows:

- Add 0.2 Chlorhexidine Diacetate

Our goal is to release Peak™ Universal Bond as a new product potentially replacing Peak™ Bond.

The Indications for Use remains the same as Peak™ Bond. New labeling and packaging have been added to reflect Peak™ Universal Bond as a new product which is an improvement over Peak™ Bond with the addition of chlorhexidine which was added to ensure long term bond strengths.

Peak Universal Bond is a dental composite material used for virtually all etching and bonding needs in restorative dentistry.

Brief Description of Testing Performed

We repeated the exact same testing as was performed on Peak™Bond (K063557). The bond strength that was tested on Peak™LC compared to Peak™ Universal bond and NexTemp using a Total Etch system and a Self Etch System. Then, all three products were thermal cycled and all parameters were again tested. The test data is included in Section IV. The test data shows that Peak™ Universal Bond has higher shear bond strengths than Peak™ Bond, which was superior to its predicates when tested in (K063557) and NexTemp.

Stability Testing for Shelf Life

Stability testing was also conducted on Peak Universal Bond and the results showed that the product has an 18 month shelf life based on accelerated stability studies conducted in R & D. The timing of seven weeks of storage at a temperature elevated 36°C above ambient is equivalent to 84.9 weeks or 19.5 months of real time shelf life.

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

JUL 1 3 2010

Ms. Diane Rogers
Regulatory Affairs Manager
Ultradent Products, Incorporated
505 West 10200 South
South Jordan, Utah 84095

Re: K100752
Trade/Device Name: Peak™ Universal Bond
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: II
Product Code: KLE
Dated: June 24, 2010
Received: June 25, 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): K100752

Device Name: Peak™ Universal Bond

Indications for Use:

Use for virtually all etching and bonding needs in restorative dentistry for patients of all ages.

Peak™ Universal Bond bonds to the following materials:

- Dentin and enamel
- Porcelain
- Metal
- Composite

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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K100752

(Posted November 13, 2003)