K111696

Section 5

SEP - 7 2011

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:	June 14, 2011

Name of the Device

Trade Name:	Opal® Band™ Cement
Common Name:	Adhesive, Bracket and Tooth Conditioner, Resin
Device Classification:	II
Classification Product Code:	DYH

Legally Marketed Predicate Devices to Which Equivalence is Claimed

The predicate device is: K950514 GC/3M Tri-Cure Glass Ionomer Orthodontic Band Cement also known as " Unitek™Multi-Cure Glass Ionomer Band Cement"

Opal® Band™ Cement is very similar to our predicate device in that both devices are intended to be used to cement orthodontic bands on to teeth. There are several other products in the market that have the same indications as these products. We chose Unitek™ Multi-Cure Glass Ionomer Band Cement as it tested the most similar to Opal®Band™ Cement.

Indications for Use: Opal® Band™ Cement uses chemical, light and glass ionomer polymerization to cement all types of orthodontic bands to the teeth.

Product Description: Opal® Band™ Cement is a triple cure, band cement which is light blue, two-part, resin based, fluoride releasing, glass ionomer orthodontic cement.
Opal® Band™ Cement is a triple cure, fluoride releasing, permanent band cement used by dentists and orthodontists to cement a variety of bands and sizes of bands onto teeth. Orthodontic bands are indicated for patients of all ages that a dentist or orthodontist deems necessary for treatment.

Similarities in the Indications for Use

Opal® Band™ Cement		Opal® Band™ Cement uses chemical, light and glass ionomer polymerization to cement all types of orthodontic bands to the teeth.
Unitek™ Multi-Cure Glass Ionomer Band Cement	K950514	Unitek™ Multi-Cure Glass Ionomer Orthodontic Band Cement is a two-part powder/liquid glass ionomer cement for orthodontic banding.

Opal® Band™ Cement is supplied in a pre-mixed syringe for easy delivery and no waste.

Unitek™ Multi-Cure Glass Ionomer Band Cement is supplied in bottles of liquid and powder that need to be mixed in a dish prior to use.

Brief Description of Testing Performed

The following bench tests were conducted during the R & D phase on Opal® Band™ Cement and compared to K950514 GC/3M Tri-Cure Glass Ionomer Orthodontic Band Cement also known as " Unitek™Multi-Cure Glass Ionomer Band Cement" Final test results are in Section 18 "Bench Testing".

a. **Flexural Strength** – This test will show the strength of the bond during stress. A higher number than our competitors is good. The modulus side of this test shows the strength at which flexing the bond occurs. Our testing shows more "give" to it as our competitor's product has more glass ionomer in it and tends to be "stiffer. We prefer the elasticity.

b. **Hardness** – This test shows the resiliency of the material to resist deformation. It is acceptable for us to stay ± 6.0 HK of our competitors range with water and ±14.0 HK in hardness without water as this shows the elastic properties of our cement.
c. **Setting Time** – This test determines the amount of time it takes for the product to be completely set. We prefer to be as close to our predicate as possible.
d. **Ambient Light Sensitivity** – This test shows the time that the product will cure in ambient light. It shows working time with the product and curing time of the product. We want higher times in this category.
e. **Sorption** – This test shows how much water the resin absorbs. We want low readings on this test. Both products show hydrophyllic properties which is indicative of their base materials.
f. **Film thickness** – testing bond strength at a defined thickness.
g. **Radiopacity** – verifying how clear the product shows up during an Xray.
h. **Soluability**- testing whether the product degrades in solutions or saliva. Look for a pass in this section.
i. **Working time** – The amount of time you have to work with the product before it starts to set-up
j. **Compressive Strength** – Measures the material's ability to not break apart under a compressive load. Prefer a higher number.
k. **Compressive Modulus** - This shows the amount of "give" when under force. We prefer a similar number to our predicate.
l. **Metal Shear** –This test checks the ability of the product to adhere to metals. We prefer a number similar to our predicate.
m. **Dimension Change** – Determines how much water is absorbed into the product. Two sets of measurements were recorded to validate our numbers.
n. **Fluoride release** – Tested fluoride release over 28 days and Fluoride burst on the first day.
o. **Fluoride Burst** – First day of measurements

Clinical Summary

A complete Clinical Summary of Opal® Band™ Cement is included in Section 20. We conducted a literature study to show safety and effectiveness of Opal® Band™ Cement. The product including different sizes and shapes can be used on any age patient when treatment is prescribed by a dentist or orthodontist. The device has the same technological characteristics compared to K950514 GC/3M Tri-Cure Glass Ionomer Orthodontic Band Cement also known as " Unitek™Multi-Cure Glass Ionomer Band Cement"

These materials have been widely used by numerous manufacturers in the dental industry.

The efficacy or suitability to the intended purpose of Opal® Band™ Cement has been demonstrated by a combination of in-house testing and side-by-side comparisons to predicate devices currently on the market. Results of our bench testing indicates that Opal® Band™ Cement performs as well or better than the predicate device currently on the market.

Summary
Risk/Benefit Review

Considering the safe history of our predicate, K950514 GC/3M Tri-Cure Glass Ionomer Orthodontic Band Cement also known as" Unitek™Multi-Cure Glass Ionomer Band Cement", Opal® Band™ Cement is substantially equivalent and considered to be a safe medical device. Our research indicates that our predicate has been used by many dentists and large group practices in the United States and purchased by a large number of international distributors. To date, there have been no reported complaints of local or systemic adverse effects associated with the use of the predicate product.

Opal® Band™ Cement was tested for biocompatibility in Cytotoxicity, Sensitization, Irritation and Genotoxicity tests according to ISO 10993-1:2009. An abstract of the testing along with signed test reports are included in Section 15 "Biocompatibility" of this submission.

In conclusion, Opal® Band™ Cement has been designed and manufactured with the intended use and claims for the product in mind. Scientific literature, etc. has been collected and evaluated to determine safety and efficacy of similar products used for the same indication. Following the clinical review as documented above, Opal Orthodontics by Ultradent Products, Inc. deems that when this device is used under the conditions and for the purposes intended, it will not compromise the clinical condition or the safety of the patient and the association with its use constitutes acceptable risks when weighed against the benefits to the patient. Therefore, the product is compatible with a high level of protection of health and safety and may be released to the market.

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

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

SEP - 7 2011

Re: K111696
Trade/Device Name: Opal® Band™ Cement
Regulation Number: 21 CFR 872.3750
Regulation Name: Orthodontic Bracket Adhesive and Tooth Conditioner
Regulatory Class: II
Product Code: DYH
Dated: June 13, 2011
Received: June 17, 2011

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): K111696

Device Name: Opal® Band™ Cement

Indications for Use:

Opal® Band™ Cement uses chemical, light polymerization and glass ionomer to cement all types of orthodontic bands to the teeth.

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)

(Posted November 13, 2003)

Susan Runner

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

510(k) Number: K111696