K131357

Section 5

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

SEP 06 2013

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

Contact Person:	Diane Rogers
Title:	Manager of Regulatory and Global Affairs
Telephone:	(800) 552-5512 x4491, (801) 553-4491
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Date Summary Prepared:	May 10, 2013

Name of the Device

Trade Name:	Peak® Z
Common Name:	Resin tooth bonding agent
Device Classification:	Class II
Classification Product Code:	KLE

Legally Marketed Predicate Devices to Which Equivalence is Claimed

The predicate device is: K091705 Primer Plus (Z Prime Plus) by Bisco Inc. located at 1100 W. Irving Park Road, Schaumburg IL 60193.

Peak® Z is very similar to our predicate device in that both devices are intended to be used as resin tooth bonding agents.

Indications for Use: Peak® Z is intended for use as a surface treatment for restorations made of the following materials:

- Zirconia
- Aluminum oxide
- Metal/Alloy
- Titanium

Product Description: Peak® Z is a single component surface treatment that enhances bond values when applied to zirconia, alumina, and metal/alloys. It contains 12-methacryloyldoeceylphosphate (MDP), which produces a chemical bond that significantly increases adhesion between a resin-based material and the bonding surface of the restoration. Peak® Zr Primer can be applied through a syringe delivery or brush and bottle.

Technological characteristics

Product	510(k) Number	Indications for Use
Peak® Z		Peak® Z is intended for use as a surface treatment for restorations made of the following materials: • Zirconia • Aluminum oxide • Metal/Alloy • Titanium
Primer plus (Z-Prime)	K091705	The principal uses of the Primer Plus are: 1. Indirect restorations (such as composite, endodontic posts, metal/metal alloys, porcelain, zirconia, alumina, ceramics, and hybrid ceramics) 2. Intraoral repairs of fractured crowns and bridges (such as metals/metal alloys, porcelain, zirconia, alumina, ceramics, hybrid ceramics, or composite resin).
Characteristics	Surface treatment to enhance restorations and repairs	Surface treatment to enhance restorations and repairs
Human Factors	Syringe delivery or brush and bottle	Brush and bottle

Biocompatibility	ISO 10993 Cytotoxicity Sensitization Irritation Genotoxicity	ISO 10993 Cytotoxicity Sensitization Irritation Genotoxicity

Peak® Z is supplied in a pre-mixed syringe for easy delivery and no waste, and also in bottles with brushes that can be directly applied to surfaces.

Primer plus is supplied in single bottles that can be directly applied to surfaces.

The patient population is intended for all ages that need a restoration or repair as prescribed by a dentist. The device is a primer that is intended to prepare surface treatments of restorations and repairs.

Brief Description of Testing Performed

The following bench tests were conducted during the R & D phase on Peak ® Z and compared to K091705 Primer Plus (Z Prime Plus) by Bisco Inc. Final test results are in Section 18 "Bench Testing".

Shear bond: This *in-vitro* test determines how well the material enhances the bonding to various surfaces compared to both the Bisco's system and the Ultradent system without a primer. This shows whether or not a primer is needed and if the R&D formulation, Peak® Z, (PAZR41) is comparable to a product that is currently on the market and is well-received.

Shear bond with artificial aging and conditions: This *in-vitro* test artificially replicates a possible extreme condition that may occur in the clinical setting. This will indicate whether or not the material is robust enough compared to a product currently on the market.

Stability: The material was tested at various data points to verify that the function of the product did not degrade under normal and accelerated conditions.

Clinical Summary

A complete Clinical Summary of Peak® Z is included in Section 20. We conducted a literature study to show safety and effectiveness of this product. The product can be used on any age patient when treatment is prescribed by a dentist. The device has the same technological characteristics compared to K091705 Primer Plus (Z Prime Plus) by Bisco Inc.
Primer Plus has been widely used by numerous dentists in the dental industry.

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

Summary
Risk/Benefit Review

Considering the safe history of our predicate, K091705 Primer Plus (Z Prime Plus) by Bisco Inc., Peak® Z 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.

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

In conclusion, Peak® Z 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, 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 Center - WO66-G609
Silver Spring, MD 20993-0002

September 6, 2013

Ultradent Products, Incorporated
Ms. Diane Rogers
Manager of Regulatory and Globel Affairs
505 West 10200 South
SOUTH JORDAN UT 84095

Re: K131357
Trade/Device Name: PEAK® Z
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: II
Product Code: KLE
Dated: June 6, 2013
Received: June 10, 2013

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 contact 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. 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,

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, 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): K131357

Device Name: Peak® Z

Indications for Use:

Peak® Z is intended for use as a surface treatment for restorations made of the following materials:

- Zirconia
- Aluminum oxide
- Metal/Alloy
- Titanium

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)

Andrew I. Steen -S
2013.09.06 09:32:53 -04'00'

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

510(k) Number: K131357

(Posted November 13, 2003)