July 13, 2021

Ultradent Products, Inc.
Adam Black
Regulatory Affairs Manager
505 W. Ultradent Drive (10200 South)
South Jordan, Utah 84095

Re: K211237
Trade/Device Name: UltraTemp Rez II
Regulation Number: 21 CFR 872.3275
Regulation Name: Dental Cement
Regulatory Class: Class II
Product Code: EMA
Dated: May 13, 2021
Received: May 14, 2021

Dear Adam Black:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael E. Adjodha, M.ChE.
Assistant Director
DHT1B: Division of Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211237

Device Name
UltraTemp Rez II

Indications for Use *(Describe)*
Indications for use:
UltraTemp REZ II is indicated for temporization of provisional prosthesis or restorative procedures (i.e. provisional crowns, bridges, inlays, and on lays).

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Ultradent Products, Inc.
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510(k) Summary-K211237

This summary of the traditional 510(k) substantial equivalence information is being submitted in accordance with the requirements of 21 CFR 807.92 UltraTemp REZ II.

I. Applicant's Name and Address

Ultradent Product, Inc.
505 West Ultradent Drive (10200 South)
South Jordan, UT 84095

Contact Person:	Mr. Adam Black
Title:	Regulatory Affairs Manager
Telephone:	801-553-4425
Cell Phone:	435-459-9302
Fax:	801-553-4609

Date Summary Prepared: 08 July 2021

II. Name of the Device

Device:	Cement, Dental
Trade/Device Name:	UltraTemp REZ II
Common Name:	Cement, Dental
Review Panel:	Dental
Regulation Number:	21 CFR 872.3275
Device Class:	Class II
Classification Product Code:	EMA

III. Device Description

UltraTemp™ REZ II temporary resin cement is a low viscosity, temporary luting/filling material featuring a hydrophilic resin-based formula which is recommended for the retention of provisional restorations of provisional prosthesis. UltraTemp REZ II temporary resin cement may also be used for temporary restorative procedures (i.e. provisional crowns, bridges, inlays, and on lays). It is available in Fast Set (1 to 2 minutes) and Regular Set (2 to 3 minutes).

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IV. Statement of Intended Use

UltraTemp REZ II is indicated for temporization of provisional prosthesis or restorative procedures (i.e. provisional crowns, bridges, inlays, and on lays)

V. Predicate Device

UltraTemp REZ II identified primary predicate: UltraTemp REZ (UltraTemp Firm, Fast and Regular Set (K080768)

VII. Comparison of Technological Characteristics

Predicate technological comparison:

The technology, delivery, and intended use of UltraTemp REZ II are substantially equivalent to the identified predicate as outlined in Table 5-1:

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Table 5-1: UltraTemp REZ II substantial equivalence comparison

Descriptive Information/ Characteristic	Predicate: UltraTemp Firm, Fast and Regular Set (K080768)	Device: UltraTemp REZ II (K211237)	Identified Characteristic Differences and Rationale for Differences
Intended Use	For temporary application of provisional crowns, bridges, inlays, and on lays.	For temporization of provisional prosthesis or restorative procedures (i.e. provisional crowns, bridges, inlays, and on lays)	No identified differences
Intended User	Licensed Dentist or Dental Professional	Licensed Dentist or Dental Professional	Same intended user. No identified differences.
Characteristics	Low viscosity, non-eugenol, resin based temporary luting and filling material	Low viscosity, resin based temporary luting and filling material	The UTR and UTRII products vary in product formulas, see below for further discussions
Types of Materials	Polycarboxylate	Polycarboxylate	N/A

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Formulation	Zinc Oxide Cement	Zinc Oxide Cement	N/A
Delivery System or Deployment Methods	Product is packaged in a dual-barrel syringe (catalyst and base) for use. When use is required, a mixing tip is attached to the dual barrel syringe, the product is then mixed within the syringe tip as it is expressed from the syringe into the treatment site. The product is workable for 2-3 minutes or 1-2 for the Regular Set configuration and Fast Set configuration respectively prior to the product becoming fully set	Same as predicate	N/A
Principles of Operation and Critical Performance Requirements	COA Release Testing: Appearance, Setting Time, Two-Spense Syringe Delivery Test	Same as predicate	N/A
Physical Properties	**<u>Ultratemp Rez Regular Set and Fast Set</u>** **Stability** (internal Procedure)**:** Accelerated in-house study performed on UltraTemp Firm Regular and Firm Fast set. 18 months shelf life at refrigerated temperatures	**<u>Ultratemp Rez II Regular Set and Fast Set</u>** **Stability:** 12 to 18 months Shelf life, 2°C - 8°C **Compression Strength** (SOP_TST_0413.03): ≤ 35 MPa and ≥ 5 MPa	N/A

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	Tensile Strength (Crown pulls) (internal Procedure)**:** Analysis performed on UltraTemp REZ regular and UltraTemp REZ fast set. Results recorded. **Regular Set:** 9.73 ± 2.44 (Lbs). **Fast Set:** 11.32 ± 6.09 (Lbs} **Compressive Strength and Modulus**(internal Procedure)**:** Analysis performed on UltraTemp REZ regular and UltraTemp REZ fast set. Results recorded. **Regular Set:** 29.25 ± 3.21 (MPa) **Fast Set:** I4.62 ± 1. 79 (MPa) **Work and cure Time Test** (internal Procedure)**:** Analysis performed on UltraTemp REZ regular and UltraTemp REZ fast set. Results recorded. **Regular Set:** 45 seconds – 4 minutes to pass TST131 **Fast Set:** 30 seconds – 2 minutes to pass TST131	**Micro Leakage** (test method as written in PRO_RD_00076.14): Minimal to no microleakage when compared to control **Radio-Opacity** (ISO4049:2019 Section 7.14): Radio-opacity ≥ 1mm Al **Film Thickness** (ISO 3107:2011 section 7.4): ≤ 25 µm **UV Fluorescence** (test method as written in PRO_RD_00071): Sample will fluoresce under UV light **Shear Bond Strength** (SOP_TST_0170.16): Control average – sample average < 15 MPa **Working/Setting Time** (SOP_TST_0131.18): **Regular Set:** Setting time ≥ 1.5 min and not ≥ 10 min. Additionally 45 seconds – 4 minutes as tested in TST131. **Fast Set:** 30 seconds – 2 minutes as tested in TST131 **Water Removal** (test method as written in PRO_TST_0413.03): Uncured chemical will easily come off glass slide after 10 seconds air/water spray	

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		<u>Ultratemp Rez II Fast Set Only</u> Acid-soluble arsenic mass fraction 2mg/kg maximum	
Patient Population	Individuals of all ages and gender and shall be assessed by the administering dental professional.	**Age:** All ages; to be assessed by administering dental professional. **Weight, gender, health and physical condition:** All Conditions; to be assessed by administering dental professional. **Part of the body interacted with:** Applied to the prepared surfaces of enamel or dentin	N/A
Biocompatibility and Safety	Tested per ISO-10993-1 and ISO-7405 Cytotoxicity, Sensitization, irritation, and Genotoxicity testing passed. Literature and testing to demonstrate product is safe when used as directed Also, Considering the intended clinical applications and the results of the studies outlined in the biocompatibility summary found in section 8.1 of TF-00251, the	Biological risks associated to patient safety for the UTRII product have been identified, assessed, and controlled/mitigated through the appropriate documentation. Chemical characterization, biocompatibility testing, and a health-based risk assessment was completed following ISO 10993-1 and subsequent standards. After review of the pertinent, objective evidence available, Ultradent Products, Inc. concludes that the biological and toxicological risks associated with the UTRII product are low and acceptable.	N/A

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	evidence for the biological safety of UltraTemp REZ, regular and fast set, is adequate and there do not appear to be any significant toxicological risks associated with this product when used according to the manufacturer's instructions. Because UltraTemp REZ, regular and fast set is for professional use only, it is our belief that the available evidence for the biocompatibility of this product is adequate and no further studies are indicated .	It can therefore be stated that the UltraTemp REZ II product has been evaluated for biological risks and the UltraTemp REZ II product has been determined to be biologically safe for its intended uses.	

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VII Conclusion:

UltraTemp REZ II product was designed and developed to be the replacement product for UltraTemp REZ. As outlined in the comparison table above, UltraTemp REZ II is similar to the identified predicate device with respect to its intended use, its Intended User, the Device Design, Types of Material used, Delivery System and or Deployment Method, Physical Properties and Patient Population. Also, UltraTemp REZ II does not introduce any new safety or efficacy issues, questions or concerns per Biocompatibility and Safety testing has been completed.

In summary it can be stated that the development of the subject UltraTemp REZ II product is based on a well-established technology in the form of the predicate UltraTemp REZ product. Based on these comparisons to the predicate device, we believe that UltraTemp REZ II is substantially equivalent to the predicate device and do not raise new concerns of safety or efficacy.