March 20, 2024

Ultradent Products, Inc.
% Dave Yungvirt
CEO
Third Party Review Group, LLC
25 Independence Blvd
Warren, New Jersey 07059

Re: K240743
Trade/Device Name: Peak Universal Bond
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin tooth bonding agent
Regulatory Class: Class II
Product Code: KLE
Dated: March 18, 2024
Received: March 18, 2024

Dear Dave Yungvirt:

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 -S

Michael E. Adjodha, MChE, RAC, CQIA
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K240743

Device Name
Peak Universal Bond

Indications for Use *(Describe)*
Use for virtually all etching and bonding needs in restorative dentistry for patients of all ages. Peak Universal Bond is used for desensitizing/sealing of tooth structure.
Peak Universal Bond adhesive bonds to the following materials:
• Dentin and Enamel
• Porcelain, Zirconia
• Metal
• Composite

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.

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510(k) Summary

Contact Details

Applicant Name: Ultradent Products, Inc.
Applicant Address: 505 West Ultradent Drive, South Jordan, UT, 84095
Applicant Contact Telephone: 801-557-1125
Applicant Contact: Dr. Carolyn Taylor
Applicant Contact Email: Carolyn.taylor@ultradent.com

Device Name

Device Trade Name: Peak Universal Bond
Common Name: Resin tooth bonding agent
Classification Name: Agent, Tooth Bonding, Resin
Regulation Number: 872.3200
Product Code(s): KLE

Legally Marketed Predicate Devices

K100752 Peak Universal Bond – KLE
K230465 Hi-Bond Universal – KLE

Device Description Summary

Peak™ Universal Bond is a bottle, syringe, or unit dose delivered bonding resin. It can be used with self-etch or with total etch techniques. It is 7.5% filled with an ethyl alcohol solvent carrier and will cure with most high intensity lights including LEDs. Peak Universal Bond adhesive contains 0.2% chlorhexidine which may ensure long term bond strengths. Its mode of action produces a mechanical occlusion of dentin tubules by the resins, thus reducing tooth hypersensitivity.

Intended Use/Indications for Use

Use for virtually all etching and bonding needs in restorative dentistry for patients of all ages. Peak Universal Bond is used for desensitizing/sealing of tooth structure.
Peak Universal Bond adhesive bonds to the following materials:
• Dentin and Enamel
• Porcelain, Zirconia
• Metal
• Composite

Indications for Use Comparison

The indications for use between the subject device and primary predicate are identical with the addition of zirconia and desensitizing/sealing of tooth structure. The secondary predicate contains both of these indications for use.

Technological Comparison

The subject device and primary predicate are identical in chemical structure and technological characteristics. The only change in this Special 510(k) application between the primary predicate and the subject device is in the intended use. The subject device includes the indications for use of bonding to zirconia as well as desensitizing/sealing the tooth structure. The secondary predicate has these indications

for use and is tested to many of the same standards as the subject device. There are some minor differences in formulation between the subject device and secondary predicate, but the standard of testing remains the same. The subject device shear bond testing has been performed to ISO 29022 and adheres to this standard. The shear bond testing of the secondary predicate was performed to ISO 11405. This standard has been withdrawn, but follows the same principles as ISO 29022 which is the updated standard for testing dental adhesives. The secondary predicate was tested for dentinal tubule blockage. The subject device was also tested for this using SEM imaging of the device applied to the tooth. The physical properties of the subject device, predicate devices, and secondary predicate device are all the same. None of the differences in the devices impact safety or efficacy of the device.

Overall, these slight differences do not introduce new questions related to product risk, nor do they impact the safety or efficacy of the subject device as compared to the predicate product. As such, the subject device can be considered substantially equivalent to the predicate device.

Non-Clinical and/or Clinical Tests Summary & Conclusions

Verification and validation testing was performed to show that the subject device is substantially equivalent to the currently marketed predicate device, Peak Universal Bond. Full verification testing to ISO 29022:2013 and SEM imaging were completed to support the additional indications for use of this device to the primary predicate in accordance with the same testing performed to support these indications in the secondary predicate, Hi-Bond Universal K230465.

All additional verification testing was performed in accordance with Risk Management Procedures outline in SOP_QA_0028 which was prepared in accordance with ISO 14971. Simulated use and validation testing was conducted by dental professionals to confirm that all aspects from usability assessments and risk management were implemented in the labeling and the design of the device itself. The conclusion of this validation testing confirmed that the subject device met the predefined user needs and the indications for use, which are identical to the primary predicate device and/or the secondary predicate. Thus the verification and validation support the conclusion that the subject device, Peak Universal Bond, is substantially equivalent to the predicate device, Peak Universal Bond (K100752).