April 30, 2026

Ultradent Products, Inc.
% Dave Yungvirt
CEO
Third Party Review Group, LLC
7 Giralda Farms, Suite 120a
Madison, New Jersey 07940

Re: K261404
Trade/Device Name: UltraEZ
Regulation Number: 21 CFR 872.3260
Regulation Name: Cavity varnish
Regulatory Class: Class II
Product Code: LBH
Dated: April 28, 2026
Received: April 29, 2026

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the Medical Device File (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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)*
K261404

Device Name
UltraEZ

Indications for Use *(Describe)*

UltraEZ desensitizing gel helps relieve and prevent tooth sensitivity from whitening treatments. It also helps with sensitivity to cold food or drinks caused by exposed roots from gum recession or worn-down teeth. UltraEZ gel is for adults with good oral health.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Contact Details

Applicant Name: Ultradent Products, Inc.
Applicant Address: 505 West Ultradent Drive, South Jordan, UT, 84095
Applicant Contact Telephone: 801-557-4425
Applicant Contact: Wendy Collard
Applicant Contact Email: wendy.collard@ultradent.com

Date prepared: April 28, 2026

Device Name

Device Trade Name: UltraEZ
Common Name: Desensitizing gel
Classification Name: Varnish, Cavity
Regulation Number: 872.3260
Product Code(s): LBH

Legally Marketed Predicate Devices

K061438 UltraEZ Desensitizing Gel– Product Code LBH
Same manufacturer

The predicate has not been withdrawn or removed from the market for reasons of safety or effectiveness.

Device Description Summary

UltraEZ™ desensitizing gel is intended to relieve and prevent tooth sensitivity from whitening treatments or cold food and drinks. It works by forming a gentle, protective layer over sensitive teeth.

The device consists of the same formulation, chemical composition, materials, and technological characteristics as the predicate device. The gel is supplied in prefilled trays for single-patient use.

No changes have been made to the formulation, materials, manufacturing process, or technological characteristics.

Intended Use/Indications for Use

UltraEZ desensitizing gel helps relieve and prevent tooth sensitivity from whitening treatments. It also helps with sensitivity to cold food or drinks caused by exposed roots from gum recession or worn-down teeth. UltraEZ gel is for adults with good oral health.

Indications for Use Comparison

The indications for use between the subject device and primary predicate are the same purpose where the Predicate is written for the dental professional and the Subject Device is written for the layperson.

Technological Characteristics Comparison

The subject device and primary predicate are identical in:

- Chemical formulation
- Materials
- Mechanism of action
- Mode of application
- Manufacturing process
- Packaging configuration

The only modification is the expansion of the intended user population to include laypersons. This modification does not alter the fundamental scientific technology or introduce new risks.

Summary of Design Control Activities

The modification (layperson use) was evaluated through the manufacturer's design control process in accordance with 21 CFR 820.30. Activities included:

- Updated design inputs for layperson comprehension
- Human factors/usability validation
- Labeling comprehension testing
- Verification of revised Instructions for Use
- Risk analysis updates (FMEA) confirming no new hazards

All acceptance criteria were met. Results support that the device can be safely and effectively used by laypersons.

Non-Clinical and/or Clinical Tests Summary & Conclusions

Because the formulation and technological characteristics are unchanged, no new bench testing was required.

The following verification and validation activities were performed to support the labeling modification:

Human Factors / Usability Validation

- **Objective:** Confirm that lay users can correctly understand and follow the Instructions for Use.
- **Methods:** Representative lay users performed simulated use tasks.
- **Acceptance Criteria:** ≥90% correct task completion; no use-related safety issues.
- **Results:** All acceptance criteria met; no use errors affecting safety or effectiveness.

Labeling Comprehension Testing

- **Objective:** Assess clarity, readability, and comprehension of revised labeling.
- **Results:** Users demonstrated accurate understanding of indications, warnings, and application steps.

Risk Management

- Updated risk analysis confirmed no new risks introduced by the change in intended user.

These data support that the device remains safe and effective for its intended use.

Biocompatibility

No changes were made to the formulation or materials. The predicate device has established biocompatibility for its intended use. A biocompatibility rationale was provided confirming that no new testing is required.

Conclusion

The UltraEZ™ Desensitizing Gel subject device is substantially equivalent to the predicate device (K061438). The modification to expand the intended user population to laypersons does not alter the intended use or technological characteristics. Design control verification and validation demonstrate that the device remains safe and effective for its intended use.