July 1, 2026

Ultradent Products, Inc.
% Dave Yungvirt
CEO
Third Party Review Group, LLC
1887 Whitney Mesa Dr.
Suite 1960
Henderson, Nevada 89014

Re: K262228
Trade/Device Name: Transcend Bulk Fill Flowable Composite
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth shade resin material
Regulatory Class: Class II
Product Code: EBF, DYH
Dated: June 29, 2026
Received: June 30, 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
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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)*
K262228

Device Name
Transcend Bulk-Fill Flowable Composite

Indications for Use *(Describe)*
Transcend™ Bulk-Fill flowable composite is used for:
• Direct and indirect restorations in both the anterior and posterior regions
• Fabrication of orthodontic attachments for aligners and bonding of lingual retainers

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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510(k) Summary

Substantial Equivalence Summary — Public Document (21 CFR 807.92)

.1. Applicant / Submitter Information

Field	Entry
Date	29 June 2026
Applicant Name	Ultradent Products, Inc.
Applicant Address	505 West Ultradent Drive, South Jordan, UT 84095
Contact Person	Ruth Gardner

2. Device Information

Field	Entry
Device Trade Name	Transcend Bulk Fill Flowable Composite
Common / Generic Name	Tooth shade resin material
Classification	Class II
Product Code	EBF DYH
Regulation Number	21 CFR 872.3690 21 CFR 872.3750

3. Indications for Use

Transcend™ Bulk Fill flowable composite is used for:

• Direct and indirect restorations in both the anterior and posterior regions

• Fabrication of orthodontic attachments for aligners and bonding of lingual retainers

4. Device Description

Transcend™ Bulk Fill flowable composite is a light-cured, radiopaque, methacrylate-based flowable bulk fill composite. Transcend Bulk Fill flowable composite is available in the Universal Body shade based on an average dentin shade designed to take on the shade of the surrounding tooth structure. Do not use Transcend™ Bulk Fill flowable composite as the occlusal surface of a restoration. It is recommended to use a packable composite as the final layer when restoring an occlusal surface. The chemistry possesses low shrinkage stress and high wear resistance. Per ISO 4049 testing, the composite has a 4 mm depth of cure. Per testing in a tooth-colored mold, the composite has a 7 mm depth of cure. Transcend Bulk Fill flowable composite has a radiopacity value of 2.3 mm of aluminum. Aluminum has a radiopacity equivalent to that of dentin. Thus, 1 mm of material having a radiopacity equivalent to 1 mm of aluminum has a radiopacity equivalent to that of dentin and 2 mm of aluminum is equivalent to enamel. Transcend Bulk Fill

flowable composite is a 56% filled by mass and 47% filled by volume thixotropic bulk fill composite with an average particle size of ~1 µm.

Transcend™ Bulk Fill flowable composite is intended to be used by trained dental professionals and can be used on patients of all ages and conditions requiring the indicated restoration and orthodontic attachment procedures other than those with known sensitivities to methacrylates or other resins. Any restrictions regarding patient populations can be found below in the Contraindications section.

5. Predicate Device(s)

Device Name	510(k) #	Applicant	Clearance Date	Regulation
Transcend	K201795	Ultradent Products, Inc	9/28/2020	21 CFR 872.3690
AlignerFlow LC	K231817	Voco GmbH	12/01/2023	21 CFR 872.3750

6. Comparison to Predicate

Characteristic	Subject Device	Primary Predicate	Secondary Predicate	Same / Different
Intended Use	Dental restorative composite material	Dental restorative composite material	Dental composite for orthodontic applications	Same
Indications for Use	Transcend™ Bulk Fill flowable composite is used for: • Direct and indirect restorations in both the anterior and posterior regions • Fabrication of orthodontic attachments for aligners and bonding of lingual retainers	Transcend universal composite is used for direct and indirect restorations in both the anterior and posterior regions.	-Retention of aligners by fabrication of aligner attachments -Bonding of lingual retainers -Occlusal build-ups	Similar Transcend™ Bulk Fill Flowable Composite shares the same intended use as both predicate devices; however, it does not include indications for occlusal build-ups.
Technology / Design Principle	• Light-cured methacrylate-based resin • Methacrylates/BisGMA, BisEMA(2), diurethane dimethacrylate, IBMA resin with glass/silinated glass fillers.	• Light-cured methacrylate-based resin • Methacrylate/dimethacrylate resin with silica/silanated silica fillers. • 24 month shelf life	• Light-cured methacrylate-based resin • Barium aluminium borosilicate glass, silicon dioxide, DDDMA, BisGMA, TEGDMA, BisEMA, fumed silica,	Similar — same fundamental technology (light-cured methacrylate-based resin); differences in formulation,

	• 48 month shelf-life		initiators, stabilisers, pigments; contains methacrylate and BHT. • Shelf-life not found in official documentation	filler, and shelf-life are present but do not raise new questions of safety or effectiveness and were evaluated through bench testing
Sterility	Non-sterile	Non-sterile	Non-sterile	Same

7. Summary of Testing

Test Category	Method / Standard	Conclusion
Bench Performance Testing	- ISO 4049 - Compressive Strength - Knoop Hardness - Depth of Cure - Water Sorption - Water Solubility - Resin Compatibility - Appearance - Light Sensitivity - Shrinkage Volume - Radio-opacity - Flexural Strength - Color Stability - Fill Volume Range - Expression Testing - Adaptability to Orthodontic attachment templates - Simulated Use: Removal from tooth - Simulated Use: Restoration procedures and orthodontic attachment procedures	Passed — all criteria met
Biocompatibility (ISO 10993)	ISO 10993-1:2018	Biocompatible — all endpoints addressed
Sterilization Validation (if applicable)	Not Applicable (non-sterile device)	N/A
Shelf Life (if applicable)	Stability testing per internal protocols	48 Months
Software V&V (if applicable)	Not Applicable	N/A

Electrical Safety/EMC (if applicable)	Not Applicable	N/A

8. Substantial Equivalence Conclusion

Transcend™ Bulk Fill Flowable Composite has the same intended use as Transcend™ Composite (K201795) and AlignerFlow LC (K231817). The primary predicate, Transcend™ Composite (K201795), supports the restorative indications and material characteristics of the subject device. The secondary predicate, AlignerFlow LC (K231817), which is classified under product code DYH, supports orthodontic applications, including fabrication of aligner attachments. The subject device shares the same fundamental technological characteristics as the predicate devices, namely the use of a light-cured, methacrylate-based composite system. Differences in formulation, filler, and shelf-life are present; while these do not raise new questions of safety or effectiveness and were evaluated through bench testing, the technological characteristics of the subject device are not identical to those of the predicate devices. These variances do not affect the substantial equivalence determination but are noted here for completeness and traceability of review documentation. Performance testing and biocompatibility data demonstrate that the device is as safe and effective as the predicate devices. Therefore, Transcend™ Bulk Fill Flowable Composite is substantially equivalent to the identified predicate devices.