September 28, 2020

Ultradent Product, Inc.
Karen Kakunes
Director Regulatory Affairs
505 West Ultradent Drive (10200 South)
South Jordan, Utah 84095

Re: K201795
Trade/Device Name: Transcend
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: Class II
Product Code: EBF
Dated: June 29, 2020
Received: June 30, 2020

Dear Karen Kakunes:

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,

For Srinivas “Nandu” Nandkumar, Ph.D.
Director
DHT1B: Division of Dental 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201795

Device Name
Transcend

Indications for Use *(Describe)*
Transcend universal composite is used for direct and indirect restorations in both the anterior and posterior regions.

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

I. Applicant's Name and Address

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

Contact Person:	Ms. Karen Kakunes, RN, BSN
Title:	Director Regulatory Affairs
Telephone (cell):	801-673-1072
Fax:	801-553-4609
Email:	karen.kakunes@ultradent.com

Date Summary Prepared: September 28, 2020

II. Name of the Device

Trade Name:	Transcend
Common Name:	Tooth Shade Resin Material
Device Classification:	II
Classification Product Code:	EBF
Regulation No.	21 CFR 872.3690

III. Device Description

Transcend is a light cured, tooth shade resin composite material (Bis-GMA based) to be used for posterior and anterior tooth restorations. Transcend is radiopaque and available in a range of dentin, enamel, and body shades. It is 81% filled by weight and 58% filled by volume and has an average particle size of 0.9µm (by weight) with narrow upper limit particle distribution.

Composite Wetting Resin is a 45% filled, radiopaque light cured wetting resin. Composite Wetting Resin helps to improve the glide of the instrument during sculpting and contouring. It may be used during the placement of composite if the composite has become dry during incremental layering, or if the oxygen inhibition layer has been removed or disturbed. The wetting agent is an accessory and, if necessary, is used in conjunction with Transcend.

IV. Statement of Intended Use

Transcend universal composite is used for direct and indirect restorations in both the anterior and posterior regions.

V. Predicate Device

The predicate device for Transcend, Amelogen Plus, is cleared under 510(k) K043119. The predicate device is also manufactured and distributed by Ultradent Products, Inc.

The reference device for the subject accessory device, Composite Wetting Resin is SeamFree, K092539, as manufactured by Apex Dental Materials.

VI. Comparison of Technological Characteristics

Predicate technological comparison:

The technology, delivery, and intended use of Transcend is substantially equivalent to the identified predicate. The technology, delivery, and intended use of the accessory device, Composite Wetting Resin, is similar to the reference device. Comparisons are outlined in Table 5-1.

Table 5-1: Substantial equivalence comparison

Characteristic	Predicate Product Amelogen Plus (K043119)	Subject Device: Transcend Subject Accessory Device: Composite Wetting Resin (K201795)	Reference Device Seamfree (K092539)	Difference
Indications for Use/Intended Use	The Amelogen Plus is a tooth shade resin composite material [bisphenol-A, glycidyl methacrylate (Bis-GMA) based] to be used for posterior and anterior tooth restorations.	Transcend is used for direct and indirect restorations in both the anterior and posterior regions. Composite Wetting Resin helps to improve the glide of the instrument during sculpting and contouring. It may be used during the placement of composite if the composite has become dry during incremental layering, or if the oxygen inhibition layer has been removed or disturbed.	Seamfree is intended to be used to lubricate restorative instruments and materials. It can be used in all dental restorations and with any methacrylate-based material.	Similar The Indications for Use of the subject device is within that of the predicate device. The indications for use of the subject accessory device is within that of the reference device in that it aids in the glide and lubricant of the instrument and composite material.
Intended user	Licensed dentist	Licensed dentist	Licensed dentist	Identical

Composition of Materials	Methacrylate based resin with FDA approved pigments Bis-GMA, GDMA Phospate, TEGDMA, BHT, Camphorquinone, Ethyl-4-Dimethlyaminobenzoate, Barium borosilicate glass powder, Aluminum Oxide C FDA Approved pigments in varying concentrations depending on composite shade: TiO2, Yellow Iron Oxide, Red Iron Oxide, Lumilux Blue, Black	**Transcend:** Methacrylate based resin with FDA approved pigments Bis-GMA, Ethoxylated (2) Bisphenol A Dimethacrylate, HDDMA, HPMA, Camphorquinone, Ethyl-4-Dimethlyaminobenzoate, Omnirad 819, OPPI, CEMA, Glass fillers FDA Approved Pigments in varying concentrations depending on composite shade: TiO2, Yellow Iron Oxide, Red Iron Oxide, Lumilux Blue, Black **Composite Wetting Resin:** DUDMA, Bis-GMA, TEGDMA, Camphoquinone, Ethyl-4-dimethylaminobezoate, BHT, Aluminum Oxide, Barium Alumina Silicate Glass	Methacrylate based resin	Similar Both the subject device and the predicate device consist mainly of fillers and methacrylates. They each have similar resins and initiators/inhibitors for appropriate curing. The subject accessory device is similar in primary composition to the reference device in that they are both methacrylate-based resins.
Delivery system	Compule, syringe	Transcend: Compule, syringe Composite Wetting Resin: syringe	Bottle, Syringe	Identical between subject and predicate device. Similar in that subject device is only available in syringe where reference device is a bottle and a syringe.
Physical property Flexural Strength	Conforms to the requirement of ISO 4049 and ADA No. 27	Conforms to the requirement of ISO 4049 and ADA No. 27	N/A	Similar Slight differences in property values, but both devices conform to the requirements of

Depth of Cure Water Sorption Water Solubility Ambient Light Sensitivity Radio – Opacity Color Stability	Conforms to the requirement of ISO 4049 and ADA No. 27 Conforms to the requirement of ISO 4049 and ADA No. 27 Conforms to the requirement of ISO 4049 and ADA No. 27 Conforms to the requirement of ISO 4049 and ADA No. 27 Conforms to the requirement of ISO 4049 and ADA No. 27 Conforms to the requirement of ISO 4049 and ADA No. 27	Conforms to the requirement of ISO 4049 and ADA No. 27 Conforms to the requirement of ISO 4049 and ADA No. 27 Conforms to the requirement of ISO 4049 and ADA No. 27 Conforms to the requirement of ISO 4049 and ADA No. 27 Conforms to the requirement of ISO 4049 and ADA No. 27 Conforms to the requirement of ISO 4049 and ADA No. 27		ISO 4049/ADA No. 27 The subject accessory device was tested with methacrylate-based composite and passed acceptance criteria.
Shelf Life	36 months @ 18-27°C	**Transcend:** 24 months @ 18-27°C Composite Wetting Resin: 40 months @ 2-8°C	Unknown	Similar Subject device has shorter shelf life to release to market as on-going stability testing is performed. Identical storage requirements.
Standards	ISO 10993, ISO 14971, ANSI ADA Standard No. 27-2016	**Transcend:** ISO 10993, ISO 14971, ISO 4049:2019, ANSI ADA 27-2016 **Composite Wetting Resin:** ISO 10993, ISO 14971	Not available	Identical between subject and predicate device.

The technological and performance characteristics of Transcend are very similar to those of the predicate device, Amelogen Plus (K043119). Transcend is a similar product, manufactured with similar or identical materials and used in the same way by the same types of users. The differences outlined above do not affect substantial equivalence.

In addition, the accessory device, Composite Wetting Resin, is similar in technology, used in the same way by the same users and with the same type of product(s) as the reference device, Seamfree (K092539).

VI. Non-Clinical Performance Data Summary

Before marketing the device, testing has been conducted to meet specified acceptance criteria.

Transcend has been designed and tested to ISO 4049:2019 Dentistry – Polymer-based restorative materials and ANSI ADA 27-2016 Polymer-based Restorative Materials. Results for each property are within the acceptable limits of the identified standard(s).

Biocompatibility testing has been assessed for both the subject device and the subject accessory device according to ISO 10993-1:2018. The following tests were identified as appropriate for both Transcend and Composite Wetting Resin: Cytotoxicity, Sensitization, Irritation, Material Mediated Pyrogenicity, Systemic Toxicity, Local effects after implantation, Genotoxicity, and Carcinogenicity with passing results for each device and endpoint.

VII. Conclusion

The device design, delivery form(s) and intended use of Transcend and the accessory device, Composite Wetting Resin, are identical or very similar to that of the predicate and reference device(s). Based on the technological characteristics and performance testing, Ultradent Products, Inc. believes Transcend is substantially equivalent to Amelogen Plus.