

K262228 Transcend Bulk Fill Flowable Composite

Jul 1, 2026
1 days to decision

K262228 · Product code: **EBF** · Dental
Source: <https://www.510kdatabase.net/k262228/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	Jun 30, 2026
Decision date	Jul 1, 2026
Days to decision	1 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ultradent Products, Inc.
Location	Salt Lake City, UT, US
Contact	Ruth Gardner
Website	https://www.ultradent.com
510(k) history	104 submissions · 104 cleared · 1992-2026

REGULATORY CONSULTANT

Consulting firm	Third Party Review Group, LLC
Contact	Dave Yungvirt

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)