

K221909 J-TempJul 1, 2022
1 days to decisionK221909 · Product code: **EBF** · Dental
Source: <https://www.510kdatabase.net/k221909/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	Jun 30, 2022
Decision date	Jul 1, 2022
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	Matthew Buck
Website	https://www.ultradent.com
510(k) history	103 submissions · 103 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)

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