FDA 510(k) Premarket Notification

K221909 J-Temp

CLEARED

Jul 1, 2022
1 days to decision

K221909 · 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