

K261404 UltraEZApr 30, 2026
1 days to decisionK261404 · Product code: **LBH** · Dental
Source: <https://www.510kdatabase.net/k261404/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Varnish, Cavity (LBH)
Date received	Apr 29, 2026
Decision date	Apr 30, 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	Wendy Collard
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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