

**K131357 PEAK Z**Sep 6, 2013  
119 days to decisionK131357 · Product code: **KLE** · DentalSource: <https://www.510kdatabase.net/k131357/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Agent, Tooth Bonding, Resin (KLE)
Date received	May 10, 2013
Decision date	Sep 6, 2013
Days to decision	119 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ultradent Products, Inc.</b>
Location	Salt Lake City, UT, US
Contact	DIANE ROGERS
Website	<a href="https://www.ultradent.com">https://www.ultradent.com</a>
510(k) history	103 submissions · 103 cleared · 1992-2026

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k131357/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 8, 2026