

**K242749 TopCEM Ceramic Primer Ceramic Coupling Agent**Nov 8, 2024  
57 days to decisionK242749 · Product code: **KLE** · DentalSource: <https://www.510kdatabase.net/k242749/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Agent, Tooth Bonding, Resin (KLE)
Date received	Sep 12, 2024
Decision date	Nov 8, 2024
Days to decision	57 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Rizhao Huge Biomaterials Company, Ltd.</b>
Location	Rizhao City, CN
Contact	Maggie Zheng
510(k) history	13 submissions · 13 cleared · 2020-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k242749/> 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 May 13, 2026