

**K012440 MODIFICATION TO CLEARFIL LINER BOND 2V**Sep 5, 2001  
36 days to decisionK012440 · Product code: **KLE** · Dental  
Source: <https://www.510kdatabase.net/k012440/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Agent, Tooth Bonding, Resin (KLE)
Date received	Jul 31, 2001
Decision date	Sep 5, 2001
Days to decision	36 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Kuraray Medical, Inc.</b>
Location	New York, NY, US
Contact	MASAYA SASAKI
510(k) history	42 submissions · 42 cleared · 2001-2012

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k012440/> 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 15, 2026