

**K013519 SIMPLE**Jan 17, 2002  
86 days to decisionK013519 · Product code: **KLE** · Dental  
Source: <https://www.510kdatabase.net/k013519/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Agent, Tooth Bonding, Resin (KLE)
Date received	Oct 23, 2001
Decision date	Jan 17, 2002
Days to decision	86 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Bisco, Inc.</b>
Location	Mchenry, IL, US
Contact	STEPHEN D SMITH
510(k) history	88 submissions · 88 cleared · 1984-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k013519/> 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 28, 2026