

**K964000 BISFIL 2B**Nov 5, 1996  
29 days to decisionK964000 · Product code: **KLE** · DentalSource: <https://www.510kdatabase.net/k964000/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Agent, Tooth Bonding, Resin (KLE)
Date received	Oct 7, 1996
Decision date	Nov 5, 1996
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Bisco, Inc.</b>
Location	Mchenry, IL, US
Contact	JAMES L SANDRIK
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/k964000/> 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