

**K101485 ALL-ETCH, ALL- ETCH WITH BAC**Aug 26, 2010  
90 days to decisionK101485 · Product code: **KLE** · DentalSource: <https://www.510kdatabase.net/k101485/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Agent, Tooth Bonding, Resin (KLE)
Date received	May 28, 2010
Decision date	Aug 26, 2010
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary
Other names	UNI- ETCH, UNI- ETCH WITH BAC; ETCH- 37, ETCH- 37 WITH BAC; DARK- ETCH, DARK ETCH (BLUE- E

**APPLICANT**

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Company	<b>Bisco, Inc.</b>
Location	Mchenry, IL, US
Contact	MICHELLE SCHULTZ- TAING
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/k101485/> 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 20, 2026