

**K935261 KOOLINER II**Jan 26, 1994  
84 days to decisionK935261 · Product code: **EBI** · DentalSource: <https://www.510kdatabase.net/k935261/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Resin, Denture, Relining, Repairing, Rebasing (EBI)
Date received	Nov 3, 1993
Decision date	Jan 26, 1994
Days to decision	84 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>GC America, Inc.</b>
Location	Alsip, IL, US
Contact	TERRY L JORITZ
510(k) history	126 submissions · 126 cleared · 1993-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k935261/> 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