

**K070697 COE SOFT**Mar 29, 2007  
16 days to decisionK070697 · Product code: **EBI** · DentalSource: <https://www.510kdatabase.net/k070697/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Resin, Denture, Relining, Repairing, Rebasing (EBI)
Date received	Mar 13, 2007
Decision date	Mar 29, 2007
Days to decision	16 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-LYONS
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/k070697/> 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