

**K010800 VERSYO.COM**May 31, 2001  
76 days to decisionK010800 · Product code: **EBI** · DentalSource: <https://www.510kdatabase.net/k010800/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Resin, Denture, Relining, Repairing, Rebasing (EBI)
Date received	Mar 16, 2001
Decision date	May 31, 2001
Days to decision	76 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Heraeus Kulzer, Inc.</b>
Location	Elkhart, IN, US
Contact	RAPHAEL JUDKINS
510(k) history	145 submissions · 145 cleared · 1988-2009

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k010800/> 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 May 20, 2026