

**K011277 HARD RELINER**Jun 26, 2001  
61 days to decisionK011277 · Product code: **EBI** · DentalSource: <https://www.510kdatabase.net/k011277/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Resin, Denture, Relining, Repairing, Rebasing (EBI)
Date received	Apr 26, 2001
Decision date	Jun 26, 2001
Days to decision	61 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>S &amp; C Polymer GmbH</b>
Location	Elmshorn, DE
Contact	JURGEN ENGELBRECHT
510(k) history	20 submissions · 20 cleared · 1995-2009

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k011277/> 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 22, 2026