

**K982537 TOKUYAMA SOFRELINER**Aug 24, 1998  
34 days to decisionK982537 · Product code: **EBI** · DentalSource: <https://www.510kdatabase.net/k982537/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Resin, Denture, Relining, Repairing, Rebasing (EBI)
Date received	Jul 21, 1998
Decision date	Aug 24, 1998
Days to decision	34 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Tokuyama America, Inc.</b>
Location	Washington, DC, US
Contact	DANIEL J MANELLI
510(k) history	22 submissions · 22 cleared · 1990-2002

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k982537/> 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 July 2, 2026