

**K001640 BIOSOFT RESIN**Jun 23, 2000  
46 days to decisionK001640 · Product code: **EBI** · Dental  
Source: <https://www.510kdatabase.net/k001640/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Resin, Denture, Relining, Repairing, Rebasing (EBI)
Date received	May 8, 2000
Decision date	Jun 23, 2000
Days to decision	46 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Biosoft International Corp.</b>
Location	Trenton, NJ, US
Contact	ROY SHU
510(k) history	1 submissions · 1 cleared · 2000-2000

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k001640/> 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