

**K922340 ENCORE SS-B**Oct 16, 1992  
150 days to decisionK922340 · Product code: **LLL** · Immunology  
Source: <https://www.510kdatabase.net/k922340/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Extractable Antinuclear Antibody, Antigen And Control (LLL)
Date received	May 19, 1992
Decision date	Oct 16, 1992
Days to decision	150 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Clark Laboratories, Inc.</b>
Location	Blairstown, NJ, US
Contact	Gary Lehnus
510(k) history	14 submissions · 14 cleared · 1992-1998

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k922340/> 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 29, 2026