

**K844743 SERATEST ENA(RNP/SM) DETERMINATION**Feb 4, 1985  
61 days to decisionK844743 · Product code: LLL · Immunology  
Source: <https://www.510kdatabase.net/k844743/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Extractable Antinuclear Antibody, Antigen And Control (LLL)
Date received	Dec 5, 1984
Decision date	Feb 4, 1985
Days to decision	61 days
Third-party review	No

**APPLICANT**

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Company	<b>Seragen Diagnostics, Inc.</b>
Location	Mchenry, IL, US
Contact	MICHAEL J SULLIVAN
510(k) history	20 submissions · 20 cleared · 1982-1987

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k844743/>; 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