

K842563 SERATEST DNA DETERMINATIONOct 25, 1984
115 days to decisionK842563 · Product code: **LKJ** · Immunology
Source: <https://www.510kdatabase.net/k842563/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antinuclear Antibody, Antigen, Control (LKJ)
Date received	Jul 2, 1984
Decision date	Oct 25, 1984
Days to decision	115 days
Third-party review	No

APPLICANT

Company	Seragen Diagnostics, Inc.
Location	Mchenry, IL, US
Contact	DANIEL E.WALKER
510(k) history	20 submissions · 20 cleared · 1982-1987

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k842563/>; Data sourced from FDA 510(k) public records (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. - Generated June 29, 2026