

**K843978 ENAII TEST KIT(SS-A(RO) & SS-B(LA)
AUTOANTIBODY**Dec 18, 1984
68 days to decisionK843978 · Product code: LLL · Immunology
Source: <https://www.510kdatabase.net/k843978/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Extractable Antinuclear Antibody, Antigen And Control (LLL)
Date received	Oct 11, 1984
Decision date	Dec 18, 1984
Days to decision	68 days
Third-party review	No

APPLICANT

Company	Behring Diagnostics, Inc.
Location	Mchenry, IL, US
Contact	JOHN E HUGHES
510(k) history	145 submissions · 145 cleared · 1976-1997

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k843978/> 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 28, 2026