

K862313 KALLESTAD SM/RNP TEST REAGENTAug 6, 1986
49 days to decisionK862313 · Product code: **LKJ** · Immunology
Source: <https://www.510kdatabase.net/k862313/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antinuclear Antibody, Antigen, Control (LKJ)
Date received	Jun 18, 1986
Decision date	Aug 6, 1986
Days to decision	49 days
Third-party review	No

APPLICANT

Company	Kallestad Laboratories, Inc.
Location	Mchenry, IL, US
Contact	KATIA BRESLAWEC
510(k) history	92 submissions · 92 cleared · 1976-1986

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k862313/>; 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