

K922157 ENCORE SS-AOct 13, 1992
159 days to decisionK922157 · Product code: LLL · Immunology
Source: <https://www.510kdatabase.net/k922157/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Extractable Antinuclear Antibody, Antigen And Control (LLL)
Date received	May 7, 1992
Decision date	Oct 13, 1992
Days to decision	159 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k922157/> 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