

K931543 ENCORE ENA COMBINED EIASep 8, 1993
163 days to decisionK931543 · Product code: LLL · Immunology
Source: <https://www.510kdatabase.net/k931543/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Extractable Antinuclear Antibody, Antigen And Control (LLL)
Date received	Mar 29, 1993
Decision date	Sep 8, 1993
Days to decision	163 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

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