

K993839 ENA PROFILE ELISA TEST SYSTEMJan 12, 2000
61 days to decisionK993839 · Product code: **LLL** · Immunology
Source: <https://www.510kdatabase.net/k993839/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Extractable Antinuclear Antibody, Antigen And Control (LLL)
Date received	Nov 12, 1999
Decision date	Jan 12, 2000
Days to decision	61 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Trinity Biotech USA
Location	Jamestown, NY, US
Contact	WAYNE KVETKOSKY
510(k) history	11 submissions · 11 cleared · 1999-2014

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