

**K924843 IMMUNODOT(R) ENA/DNA AUTOIMMUNITY
SCREENING PANEL**

Dec 1, 1992
64 days to decision

K924843 · Product code: LLL · Immunology
Source: <https://www.510kdatabase.net/k924843/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Extractable Antinuclear Antibody, Antigen And Control (LLL)
Date received	Sep 28, 1992
Decision date	Dec 1, 1992
Days to decision	64 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	General Biometrics, Inc.
Location	San Diego, CA, US
Contact	BRYAN L KIEHL
510(k) history	23 submissions · 23 cleared · 1989-1992

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Device record: <https://www.510kdatabase.net/k924843/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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