

K934705 OPUS NAPANov 22, 1993
53 days to decisionK934705 · Product code: **LAN** · Toxicology
Source: <https://www.510kdatabase.net/k934705/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, N-acetylprocainamide (LAN)
Date received	Sep 30, 1993
Decision date	Nov 22, 1993
Days to decision	53 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Pb Diagnostic Systems, Inc.
Location	Westwood, MA, US
Contact	NANCY M JOHANSEN
510(k) history	35 submissions · 35 cleared · 1988-1994

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