

K934762 OPUS PROCAINAMIDE TEST SYSTEMJul 20, 1994
289 days to decisionK934762 · Product code: **LAR** · Toxicology
Source: <https://www.510kdatabase.net/k934762/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Procainamide (LAR)
Date received	Oct 4, 1993
Decision date	Jul 20, 1994
Days to decision	289 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k934762/> 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