

K943980 IL TEST PHENYTION CALIBRATORSMay 1, 1995
328 days to decisionK943980 · Product code: **DIP** · Toxicology
Source: <https://www.510kdatabase.net/k943980/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Diphenylhydantoin (DIP)
Date received	Jun 7, 1994
Decision date	May 1, 1995
Days to decision	328 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Instrumentation Laboratory CO
Location	Mchenry, IL, US
Contact	WALLIS W CADY
510(k) history	321 submissions · 320 cleared · 1976-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k943980/> 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 15, 2026