

K945725 PHENYTION EIA TESTFeb 3, 1995
73 days to decisionK945725 · Product code: **DIP** · Toxicology
Source: <https://www.510kdatabase.net/k945725/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Diphenylhydantoin (DIP)
Date received	Nov 22, 1994
Decision date	Feb 3, 1995
Days to decision	73 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Diagnostic Reagents, Inc.
Location	Walker, MI, US
Contact	YUH-GEN TSAY
510(k) history	66 submissions · 66 cleared · 1982-1998

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