

K904815 QMS TM- PHENYTOINNov 6, 1990
13 days to decisionK904815 · Product code: **DIP** · Chemistry
Source: <https://www.510kdatabase.net/k904815/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Diphenylhydantoin (DIP)
Date received	Oct 24, 1990
Decision date	Nov 6, 1990
Days to decision	13 days
Third-party review	No

APPLICANT

Company	Seradyn, Inc.
Location	Indianapolis, IN, US
Contact	MICHAEL J SULLIVAN
510(k) history	28 submissions · 28 cleared · 1988-2007

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