

**K973414 ACE PHENYTOIN REAGENT, AED CALIBRATORS**Nov 4, 1997  
56 days to decisionK973414 · Product code: **DIP** · Toxicology  
Source: <https://www.510kdatabase.net/k973414/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Diphenylhydantoin (DIP)
Date received	Sep 9, 1997
Decision date	Nov 4, 1997
Days to decision	56 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Schiapparelli Biosystems, Inc.</b>
Location	Fairfield, NJ, US
Contact	STEVEN DALESSIO
510(k) history	24 submissions · 24 cleared · 1993-1999

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