

K011347 EMIT 2000 PHENYTOIN ASSAY, MODEL 0SR4A229May 17, 2001
15 days to decisionK011347 · Product code: **DIP** · Toxicology
Source: <https://www.510kdatabase.net/k011347/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Enzyme Immunoassay, Diphenylhydantoin (DIP)
Date received	May 2, 2001
Decision date	May 17, 2001
Days to decision	15 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Syva Co.
Location	Mchenry, IL, US
Contact	SUSAN COLLINS
510(k) history	448 submissions · 447 cleared · 1976-2001

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