

**K864925 EMDS TM PHENYTOIN (PTN) TESTPACK, ITEM  
#67676/95**Jan 7, 1987  
22 days to decisionK864925 · Product code: **DIP** · Toxicology  
Source: <https://www.510kdatabase.net/k864925/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Diphenylhydantoin (DIP)
Date received	Dec 16, 1986
Decision date	Jan 7, 1987
Days to decision	22 days
Third-party review	No

**APPLICANT**

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Company	<b>Em Diagnostic Systems, Inc.</b>
Location	Walker, MI, US
Contact	RAYMOND L MILLER
510(k) history	288 submissions · 288 cleared · 1984-1994

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k864925/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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