

**K963840 CEDIA PHENYTOIN II ASSAY**Nov 20, 1996  
57 days to decisionK963840 · Product code: **DIP** · Toxicology  
Source: <https://www.510kdatabase.net/k963840/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Diphenylhydantoin (DIP)
Date received	Sep 24, 1996
Decision date	Nov 20, 1996
Days to decision	57 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Boehringer Mannheim Corp.</b>
Location	Mchenry, IL, US
Contact	Yvette Lloyd
510(k) history	340 submissions · 340 cleared · 1976-1999

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k963840/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 22, 2026