

**K955873 ACS PHENYTOIN ASSAY**Mar 11, 1996  
76 days to decisionK955873 · Product code: **LGR** · Toxicology  
Source: <https://www.510kdatabase.net/k955873/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fluorescence Polarization Immunoassay, Diphenylhydantoin (total) (LGR)
Date received	Dec 26, 1995
Decision date	Mar 11, 1996
Days to decision	76 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ciba Corning Diagnostics Corp.</b>
Location	East Walpole, MA, US
Contact	STEVEN R RAKITIN
510(k) history	125 submissions · 125 cleared · 1986-1996

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