

K843209 PHENYTOIN ACA ANALYTICAL TEST PACKOct 11, 1984
57 days to decisionK843209 · Product code: **DIP** · Toxicology
Source: <https://www.510kdatabase.net/k843209/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Diphenylhydantoin (DIP)
Date received	Aug 15, 1984
Decision date	Oct 11, 1984
Days to decision	57 days
Third-party review	No

APPLICANT

Company	E.I. Dupont DE Nemours & Co., Inc.
Location	Mchenry, IL, US
Contact	CAROLYN L KRUER
510(k) history	253 submissions · 252 cleared · 1976-1996

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